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Towards the National Health Assembly II

Booklet 5

New Technologies in Public Health - Who pays and who benefits?

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New Technologies in Public Health – Who pays and who benefits?

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Section II - SAMA Resource Group for Women & Health
Section III - Dr. B.Ekbal (former Vice Chancellor of Kerala University)

These contributions have been made possible because of the contributions and the research of many institutions, organizations, and individuals participating in the Jan Swasthya Abhiyan (People's Health Movement) in India

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Introduction

This booklet discusses from the viewpoint of People's Health Movement, some important examples of development and use of relatively recent health technologies.

Part I of this booklet written by Dr. Anant Phadke of SATHI-CEHAT, Pune deals with the issues related to the use of three newer vaccines in the Public Health System in India - the hepatitis-B vaccine, the Oral Polio Vaccine (OPV) and the anti-rabies vaccine. The first two examples relate to overzealous, wrong use of the vaccines and the third example tells us how the MNCs can, in pursuit of their profits, block the use of a good technique.

Part II of the booklet prepared by the Sama team in Delhi analyses how the Assisted Reproductive Technology is promoted and used to serve the interests of the medico-industrial lobby and examines the various implications- social, medical , ethical; that this has on the lives of women.

Part III of this booklet penned by Dr. B.Ekbal, the National Convenor of the Jan Swasthya Abhiyan, deals with the tremendous potential of the new Information Technology in health care and of genomics; but how social regulation of these technologies is so very important.

These three parts appear independent of one another. But there is an underlying common thread - the People's Health Movement is for the development and use of new health technologies for the benifit of common people. However, it is against technological innovations being used mainly towards profit making, as they then have the potential of becoming instruments of control and reduce people to being passive consumers. It is in this context that the above parts have been put together.

NATIONAL COORDINATION COMMITTEE MEMBERS

1. All India People's Science Network (AIPSN)
2. All India Drug Action Network (AIDAN)
3. Asian Community Health Action Network (ACHAN)
4. All India Democratic Women's Association (AIDWA)
5. Association for India's Development (AID India)
6. Bharat Gyan Vigyan Samiti (BGVS)
7. Breastfeeding Promotion Network of India (BPNI)
8. Catholic Health Association of India (CHAI)
9. Centre for Community Health and Social Medicine , JNU
10. Christian Medical Association of India (CMAI)
11. Forum for Creche and Child Care Services (FORCES)
12. Federation of Medical Representative Associations of India (FMRAI)
13. Joint Women's Programme (JWP)
14. Medico Friends Circle (MFC)
15. National Alliance of People's Movements (NAPM)
16. National Federation of Indian Women (NFIW)
17. National Association of Women's Organizations (NAWO)
18. Ramakrishna Mission (RK)
19. SAMA
20. Support for Advocacy and Training in Health Inititiatives (SATHI)
21. Voluntary Health Association of India (VHAI)

Participating Organizations

Over 1000 organizations concerned with health care and health policy from both within and outside the above networks, have joined the Jan Swasthya Abhiyan campaign as participating organizations.

What is the Jan Swasthya Abhiyan?

In 1978 at Alma Ata, the governments of the world came together to sign the Alma Ata Declaration that promised "Health for All by 2000". However this promise was never taken very seriously and was subsequently marginalised in health policy discussions.

As the year 2000 approached it appeared that "Health for All by 2000" was quietly being forgotten by governments around the world. To remind people of this forgotten commitment the First People's Health Assembly was organised in Savar, Bangladesh in December 2000 . The People's Health Assembly was a coming together of people's movements and other non-government civil society organisations all over the world to reiterate the pledge for Health for All and to make governments take this promise seriously. The assembly also aimed to build global solidarity, and to bring together people's movements and organisations working to advance the people's health in the context of policies of globalisation.

The national networks and organisations that had come together to organize the National Health Assembly, decided to continue and develop this movement in the form of Jan Swasthya Abhiyan (People's Health Movement). Jan Swasthya Abhiyan forms the Indian regional circle of the global People's Health Movement. Now, six yeras later, it is time to take stock of the changes in the Health Sector as well as the progress of the Movement. Thus the plan to have the National Health Assembly II.

Despite medical advances and increasing average life expectancy, there is disturbing evidence of rising disparities in health status among people worldwide. Enduring poverty with all its facets and in addition, resurgence of communicable diseases including the HIV/AIDS epidemic, and weakening of public health systems is leading to reversal of previous health gains. This development is associated with widening gaps in income and shrinking access to social services, as well as persistent racial and gender imbalances. Traditional systems of knowledge and health are under threat.

These trends are to a large extent the result of the inequitable structure of the world economy, which has been further skewed by structural adjustment policies, the persistent indebtedness of the South, unfair world trade arrangements and uncontrolled financial speculation - all part of the rapid movement towards inequitable globalisation. In many countries, these problems are compounded by lack of coordination between governments and international agencies, and stagnant or declining public health budgets.

Within the health sector, failure to implement primary health care policies as originally conceived has significantly aggravated the global health crisis.

These deficiencies include:

- A retreat from the goal of comprehensive national health and drug polices as part of overall social policy.
- A lack of insight into the inter-sectoral nature of health problems and the failure to make health a priority in all sectors of society.
- A failure to promote participation and genuine involvement of communities in their own health development.
- Reduced state responsibility at all levels as a consequence of widespread and usually inequitable policies of privatisation of health services.
- A narrow, top-down, technology-oriented view of health and increasingly viewing health care as a commodity rather than as a human right.
- It is with this perspective that the organisations constituting Jan Swasthya Abhiyan have come together to launch a movement, emerging from the Peoples Health Assembly process. Some objectives that this coalition set for itself (which are set out in detail in the Peoples Health Charter) can be listed briefly as below:
- Jan Swasthya Abhiyan aims to draw public attention to the adverse impact of the policies of iniquitous globalisation on the health of Indian people, especially on the health of the poor.
- Jan Swasthya Abhiyan aims to focus public attention on the passing of the year 2000 without the fulfillment of the 'Health for All by 2000 A.D.' pledge. This historic commitment needs to be renewed and taken forward, with the slogan 'Health for All - Now!' and in the form of the campaign to establish the Right to Health and Health Care as basic human rights. Health and equitable development need to be reestablished as priorities in local, national, international policy-making, with Primary Health Care as a major strategy for achieving these priorities.
- In India, globalisation's thrust for privatisation and retreat of the state with poor regulatory mechanisms has exacerbated the trends to commercialise medical care. Irrational, unethical and exploitative medical practices are flourishing and growing. The Jan Swasthya Abhiyan expresses the need to confront such commercialisation,
- In the Indian context, top down, bureaucratic, fragmented techno-centric approaches to health care have created considerable wastage of scarce resources and have failed to deliver significant health improvements. Jan Swasthya Abhiyan seeks to emphasize the urgent need to promote decentralisation of health care and build up integrated, comprehensive and participatory approaches to health care that places "Peoples Health in Peoples Hands".

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SECTION I

Public Heath
Is it just Vaccines?

INTRODUCTION

Health Service is one of the essential services and yet today like other services, it is largely a commercialized service. Moreover, it has been dominated by multinationals through the pharma and equipment manufacturing industries and this influence of the profit-hungry multinationals, imperialist forces has adversely affected our health services. This is true for even in case of use of newer technological innovations in the field of Public Health. Even in the field of Public Health, multinationals develop new products and market them all over the world to compete with others to earn more and more profits. In doing so they put profits first and taking care of the interests of humanity, especially of the third world countries is only a side product. In their lust for profits they would not mind thrusting inappropriate technology on to the people or withholding newer innovations depending upon their strategic plans. During the last one decade, we have seen three such examples in the field of Public Health of how "profits first" strategy has worked against the people's interests and how some officials of the government, some experts have allied with the imperialist forces to sacrifice the interests of the Indian people. The three examples are - Polio eradication campaign, Universal Hepatitis-B vaccination strategy (imposing of inappropriate technological choice) and non-availability of the cheaper, intradermal vaccine preparation for prevention of rabies after dog-bite.

Let us examine each of these cases one-by-one, beginning with a brief on Rabies Vaccines in India.

1. Rabies Vaccines in India

"Pharma MNC's Double standards - at the cost of a nation and its people"

The example of the behaviour of the MNCs about the use of rabies vaccine In India vividly illustrates how pharmaceutical MNCs indulge in double standards and how Indian pharma companies follow the MNCs in their lust for higher profits, and how the Indian Drugs Controller, connives and at abets this anti-people behaviour.

Till last year (2005) the course of injections given to a person with dog-bite consisted of 10-14 injections into the abdomen. But now they give a course of only five injections into the arm. Why has this change occurred?

This should begin with a small clarification - This rabies vaccine injection is not given "into the abdomen" but only into the thick layer of fat below the abdominal skin so that there would be less pain due to this larger dose of injection of 5ml. each time for a course of 10-14 injections. The intestines and inside the abdominal wall, away from this site.

Until recently (June 2005), the rabies vaccine administered in Indian public health centres was of the older, obsolete variety. It was prepared by injecting the rabies virus into the sheep's brain to grow them there. Then the extract of such sheep's brain would be treated with chemicals in such a manner that the product would contain the killed rabies viruses. This vaccine when injected into a person would induce resistance in that person without causing this dreaded disease. Since this vaccine contained 'foreign-protein' from the sheep's brain, it can cause allergic reaction affecting the person's brain (Allergic Encephalo Myelitis) - a very serious condition. This occurs in one out of 5000 persons receiving this vaccine. In India every year there are about 3 million cases of suspected rabid dog bite and hence annually about 600 cases of this Allergic Encephalo Myelitis would occur due to this sheep brain vaccine

invented by Semple. Thanks for the biotechnological innovation the scientists were able to develop a safe vaccine by growing this rabies virus on embryonic tissue, human or animal. This cell culture Rabies vaccine therefore replaced the sheep brain vaccine in the developed countries. In India, the private practitioners started giving this newer, Cell Culture Vaccine more than a decade ago. In the Public Health Centres, this change has occurred late, i. e. from June 2005. Thanks to Public Interest Litigation and due to lobbying of certain groups close to the manufacturers of the cell-culture vaccine, the govt. finally decided to replace the use of sheep brain vaccine by the cell-culture vaccine in its health care centres from June 05.

In India, this did not happen because the price of cell-culture vaccine which has been monopolised by the MNCs has been very high and a course of five injections of this cell-culture vaccine would lost Rs. 1500 for the vaccine alone, as compared to about Rs. 225 for a course of 14 injections for the vaccine cost alone.

This sheep brain vaccine was not only unsafe but was also more troublesome- a course of 10-14 injections of 5ml each means 14 painful visits to the doctor! But thanks to the monopoly profiteering of the MNCs (Aventis and Chiron) and the apart of the Indian Government, this obsolete, inconvenient unsafe vaccine continued in Indian public health facilities. It has been available in the private market but has been too costly for most Indians.

The old rabies vaccine had its problems; but it was at least available free of charge in public health centres to all citizens. But since middle of last year (2005) in most such centres, the 'dog-bite injection' is available free of charge only to those who hold the yellow, Below Poverty Line (BPL) card. Why?

As mentioned above, the cell-culture vaccine has been more than six times costlier than the sheep brain vaccine. However, since rabies is an invariably fatal disease and since suspected rabid dog bite is very common in India, the Indian Govt. should have manufactured this vaccine in public sector to make it available for the Indian people and then should

have also negotiated with the private companies to reduce their prices to a reasonable level. If the Govt. itself is able to produce a part of India's requirement, in the public sector at lower cost and is going to buy in bulk the test, of the requirement, their buying price of the cell-culture vaccine would have been much less. However, the cell-culture vaccine is very costly. The Govt. did not make any such efforts to reduce its price, nor has it decided to like its budget substantially for this life saving measure. It rather decided to make the cell-culture rabies vaccine available free of charge only to those with BPL cards.

It is difficult for the Govt. to increase its expenditure six times on this injection. Isn't there an alternative?

Yes, apart from pressurizing the Pharma companies to reduce their prices of this vaccine, the free expense of this vaccine can be reduced by using an innovative method and its use. If this vaccine is given intradermally i.e. within the two layers of the skin, (the BCG vaccine against tuberculosis is given to all newborns in this way) it requires only one fifth of the usual dose and yet it is equally effective.

This Intra Dermal (I.D.) route is scientifically well established. The WHO has been recommending it as an option since 1992.[1] Thanks to the pioneering work of the Thailand Red Cross Society, one of Intra Demand Regimens is now very well established. It consists of giving 0.1ml injection of the Chick Cell Embryo Vaccine intradermally at two sites on the arm at a time on the first, third, 7th, 28th and 90th day of the suspected rabid dog bite. This means a total dose of 0.8 ml of this vaccine in five injection visits to the doctor.

This I.D. regimen is now routinely taught to the doctors during their graduation and for many years it has been recommended by the mostly widely used undergraduate textbook of Preventive and Social Medicine, by Park and Park.[2]

To be sure, to give an injection within the two layers of the skin must be a very skilled, delicate operation. Can the staff in the Public Health Centres do this?

For decades, every year BCG Vaccine has been given within the two layers of the very thin, tender skin of millions of newborns in India by the paramedic staff in the Public Health Service. So with a little training of paramedics and doctors in Public Health Facilities or in the private sector, they can certainly give the rabies vaccine by I.D. route by using a special small syringe and needle as used for BCG vaccination or for giving very small dose of insulin injection for some diabetic patients.

Research has shown that even if by mistake, this vaccine is injected below the skin, instead of within the two skin layers, this does not reduce its efficacy.[3] In Thailand, thousands of persons have received this I.D. vaccine without any problems.

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[1] WHO Expert Committee on Rabies: Eighth report (WHO TRS: 824), 1992. p 25, WHO, Geneva

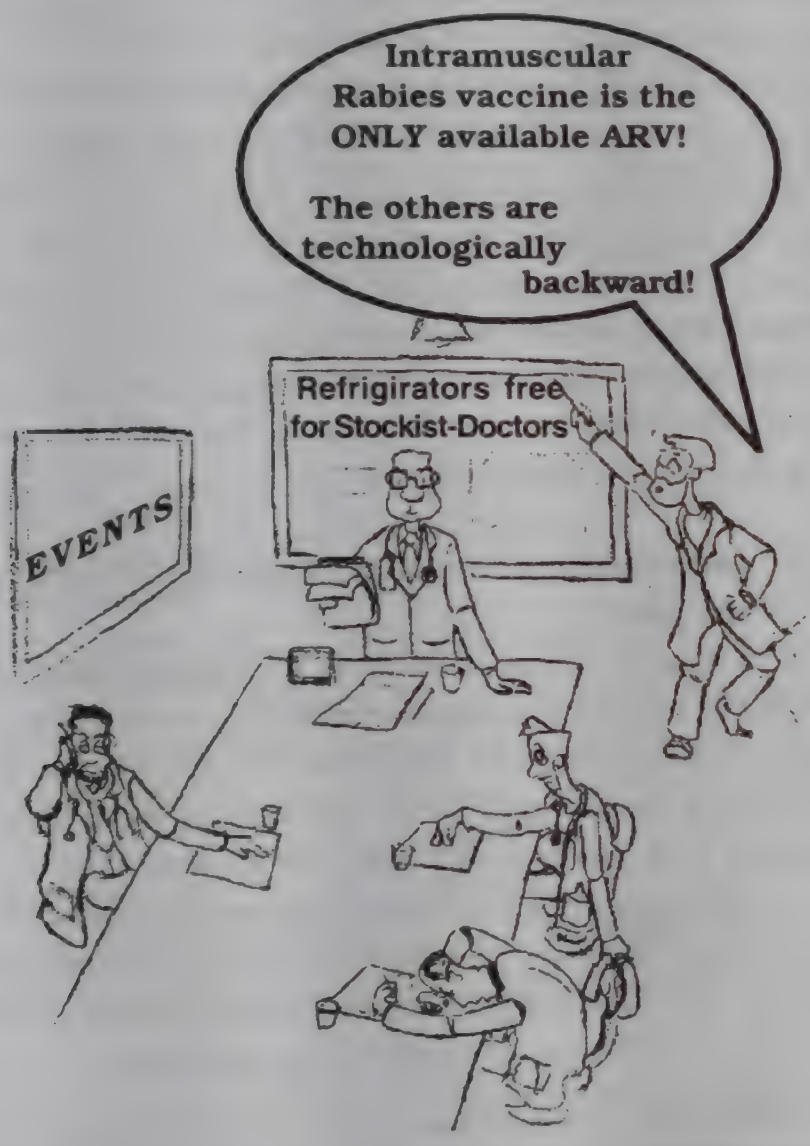
[2] Park's textbook of preventive and social medicine. 18th edition, 2005, p. 323.

[3] P. Phanuphak, P. Khaoplod, M. Benjavongkulchai, S.Chutivongse, & H. Wilde. What happens if intradermal injections of rabies vaccine are partially or entirely injected Subcutaneously? World Health Organization 1990.

Why then the Indian doctors either in the private or public sector have not been using this I.D. regimen?

The reasons are very unfortunate, yet revealing-

The concerned pharma MNCs -Aventis and Chiron have indulged in the typical MNC double standards. **"Rabipur" and "Verorab"** the two brands marketed by these two MNCs have been registered by these MNCs for both intramuscular as well as for intradermal use. Even the WHO, in its recommendation for use of I.D. route has mentioned Rabipur


Intramuscular Rabies vaccine is the ONLY available ARV!
The others are technologically backward!
Refrigirators free for Stockist-Doctors
EVENTS

A typical CME program by a rabid-pharma company

specifically for I.D. use also.[4] But in India, the same Rabipur and Verorab have been registered by these MNCs only for intramuscular use! In their "educational" or promotional/propaganda material, these companies do not mention about the I.D. route at all! Most doctors have forgotten about what may have been taught in the medical college and have been brain washed by these pharma companies and hence are currently even unaware that the I.D. option exists! Many senior doctors became graduates before the I.D. route was introduced into the medical curriculum. They have never been exposed to the fact that the equally effective and safe I.D. regimen exists because if they at all attend any of the Continuing Medical Education programmes organised by their own associations, the I.D. regimen will not be talked about in these 'scientific sessions' during any discussion on rabies vaccination! This is because these conferences are sponsored by these companies who do not want doctors to even know that the I.D.regimen exists. This is because if I.D. regimen is adopted, amount of vaccine sold and hence their profits would diminish.

Anand Development Dairy Board has entered the area of manufacture of cell-culture vaccine. But this Indian outfit has also been silent or the I.D. route for rabies vaccine!

Can't the government force these companies to register their brands for I.D. use also?

Mr. Ashwini Kumar, Drugs Controller is widely believed to be a pro-industry official and it is no surprise that he has done nothing on his own to safeguard the interests of the Indian People. He has not sent these MNCs even a show-cause notice questioning them about their double standards and has not put pressure so that they apply for registration the I.D. formulation of the rabies vaccine. Secondly since the govt. is the largest buyer of the anti-rabies vaccine, it can announce that it will buy the ARV from those companies which include I.D. use on its label. But the govt. did not act at all in this direction.

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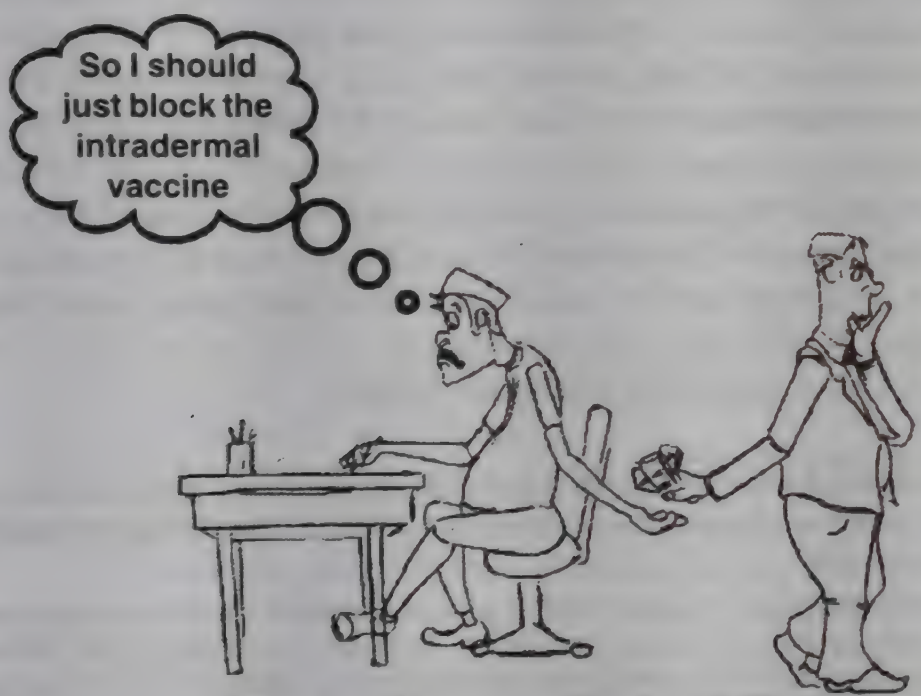
[4] WHO Recommendations on Rabies Post-Exposure Treatment and the Correct Technique of Intradermal immunization against Rabies. World Health Organization, Emerging and other Communicable Diseases, Surveillance and Control. http://www.who.int/emc.

But haven't any social activists, social work organization taken up this issue? What has been the response of the authorities?

Yes! They have. For example, in October 05, the Jan Swasthya Abhiyan wrote to the Health Minister and the Drugs Controller, with the demand to ask these companies to include intra dermal use also in their label for the Rabies. Vaccine. It also lodged complaint with the National Human Rights Commission in January 06. Secondly during the national consultation meeting on 3rd March 06, convened by the NHRC, this issue was again raised by the JSA. The print and electronic media carried the JSA criticism. It is partly because of this public criticism and due to the pressure from NHRC, the Drugs controller finally acted. He issued a letter to the concerned companies permitting them to use.

This letter however puts a ridiculous condition that ID route can be used in Health Centres where more than 50 cases of dog bite come every day! There is absolutely no rational reason for putting this pre-condition. Secondly, most Public Health Centres do not receive more than 50 cases of dog bite a day and hence they will not be able to use the I.D. regimen! The job of the Drugs Controller is to allow or reject the use of any medicine, and not to put any such ridiculous condition! This letter of the D.C. neither asks the companies to include the I.D. use in



Drugs Uncontroller's Office

their label of ARV, by mentioning the instruction- 'For intramuscular and intradermal use' nor does it ask them to manufacture 0.1ml/0.2 ml ampoules, as has been the case in the US for the I.D. use. Hence the current one ml ampule requires that in a health centre, 5-6 cases are required daily so that all the vaccine contained in this one ml. ampule is used and there is no wastage. (One case requires only 0.1 ml to 0.2 ml of vaccine at one time for I.D. use.) Hence the D.C. must. But this has not been done despite the clear, specific demand by the Jan Swasthya Abhiyan. Till these demands of the JSA are met, most health centres will not be able to use economically the Cell-Culture vaccine for I.D use. If the demands made by JSA and by its constituent organizations like the All India Drug Action Network (AIDAN) are met, the government's expense on the Cell-Culture vaccine would reduced by 80% and hence the govt. would be able to give free of charge, this life saving vaccine to all the cases of suspected rabid dog bite that come to the Public Health Facilities, with very little increase in its budget for the ARV vaccine. But there has been so much of unnecessary delay in taking these decisions! Initially the argument for the delay in taking decision of allowing I.D. use was that feasibility studies in India were needed for use of I.D. use of ARV and a Jain committee was set up in September 03 to study the matter. This was despite the fact that studies in India had already confirmed that the I.D. route is effective and safe.[5, 6] Two years passed without any decision, though any such committee could have given the recommendation in a few months by launching once more, whatever studies it wanted. But this did not happen though this issue is of life and death for thousands of patients every months. Finally, coming under intesnse pressure from the JSA and other social action groups, after a delay of 2 years the D.C. came out with a queer order, protecting the companies further that they can continue to sell more of the less advanced and more profitable IM rabies vaccine.

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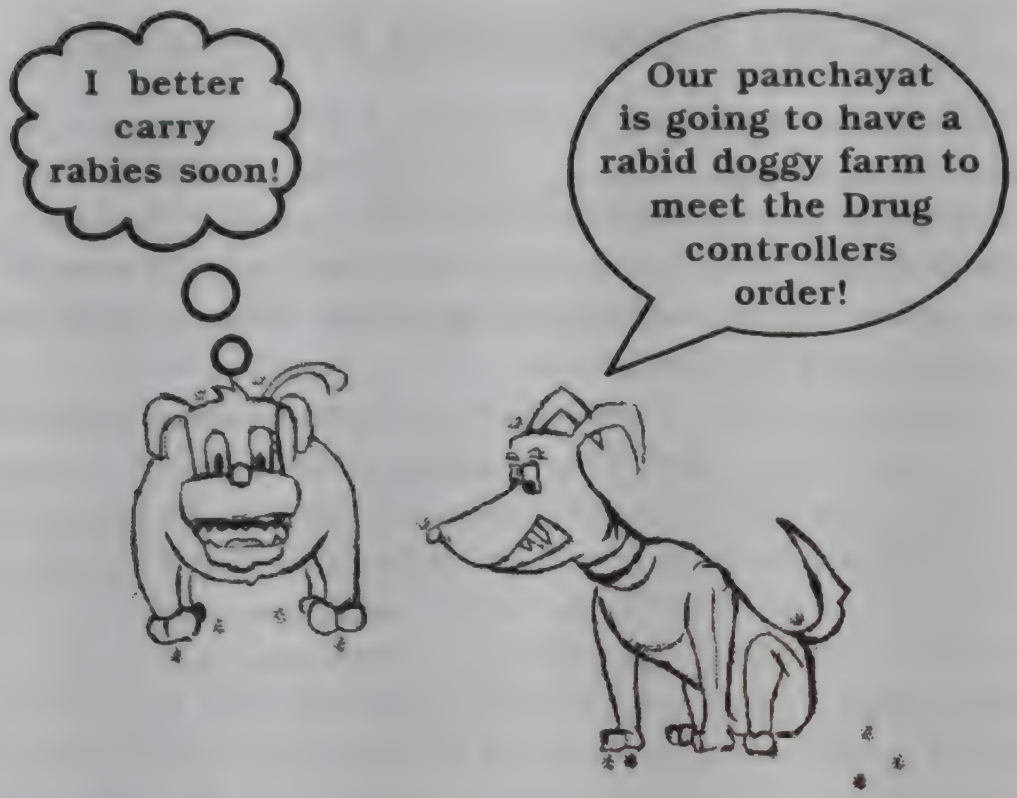
[5] Madhusudana S N, Saha S M, Sood M, Saxena SN. Multisite intradermal vaccination using tissue culture vaccine as an economical prophylactic regimen against rabies. IJMR; 1988 Jan: 1-4.

[6] Chhabra Mala, Ichhpujani RL, et al, Safety and immunogenicity of the intradermal Thai Red Cross (2-2-2-0-1-1) post exposure vaccination regimen in the Indian population using purified chick embryo cell rabies vaccine. Indian Journal of Medical Microbiology. 2005 Jan: 24-28



Now what should be one?

These delaying tactics of the D.C. have to be exposed and we need to put pressure on the D.C. as well as other the health officials so that

1. The concerned companies include in their label for the cell-culture vaccine the instruction "for intramuscular and Intradermal use" and

2. They manufacture 0.1 ml and 0.2 ml ampules at reasonable prices for I.D. use.

We should also demand an inquiry and punishment to the guilty for this unnecessary delay. This will happen if there is sufficient public pressure. This is exactly what the JSA is attempting to do.

What can I do to help this campaign?

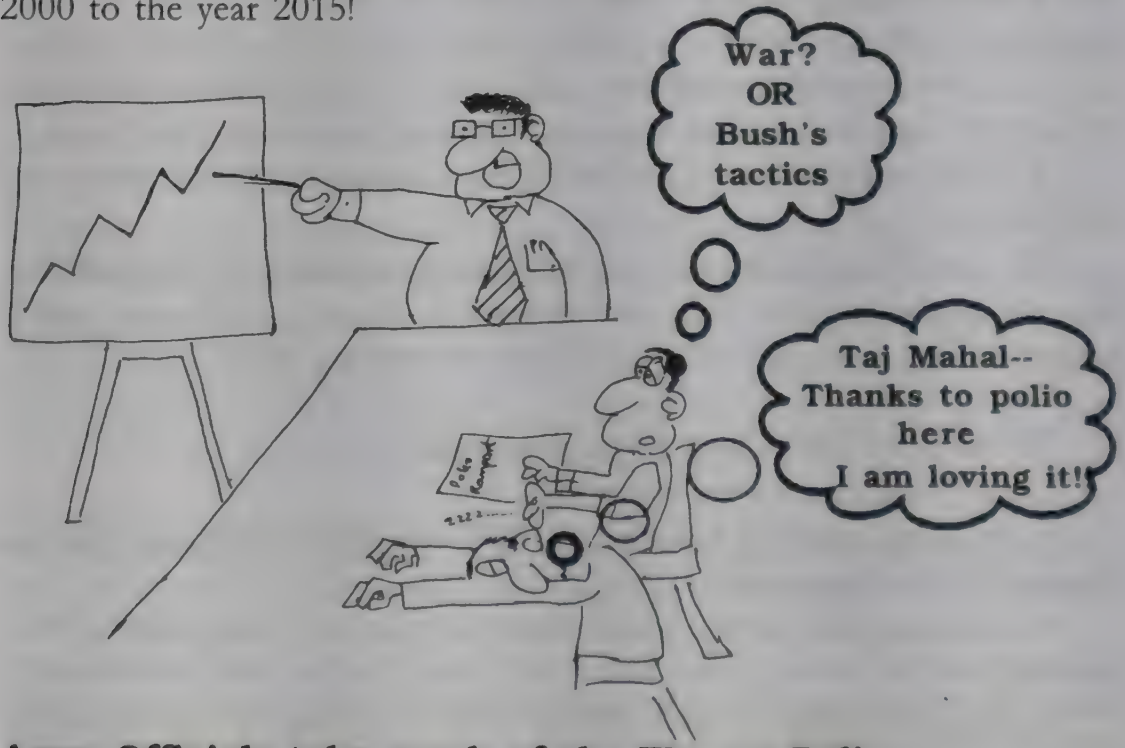
Join it! You can do the following-

- Sign the attached letter to the D.C. the Health Minister and the Human Rights Commission.
- Publicize this MNC-double standard and the complicity of the D.C.
- Approach the elected representative in your area to convince him/her to raise this issue with the concerned authorities.

2. Polio Eradication Programme

For the last few years, there has been so many appeals on the radio, TV, news-papers urging people to get the Oral Polio Vaccine to their small children. It has been said every year that like smallpox, polio is about to be eradicated. But the repeated rounds of vaccination seem to continue year after year. When is polio going to be eradicated from India?

No! Polio can not be eradicated from India by vaccination alone! Certain experts have misled the goyernment to believe that Polio can be eradicated from India by vaccination alone. Despite the government spending thousands of crores on this Polio Eradication Campaign for making so much of efforts to give Oral Polio Vaccine to each and every child, there is no chance that Polio can be eradicated from India in this manner. Many experts are now saying that this hard fact has to be accepted. Some experts like Dr. Jecob Johnfrom the Indian Academy of Pediatrics are now advocating a shift to using the injectable polio vaccine and the shifting of this date for eradication from the original date of 2000 to the year 2015!



Agra: Officials take stock of the War on Polio

But to be sure, there must have been good scientific grounds for the experts for their recommendation to the India government to launch this Eradication Campaign! What was the rationale given for launching this campaign?

Eradication of an infectious disease means not only reducing the incidence of the disease to zero but also complete wiping off/elimination from human environment, of the germ that causes this disease. When this occurs, no measures are then required to prevent the disease; this disease is eliminated forever. This is how in 1997 the International Workshop in Dahlem on the 'Eradication of Infectious Diseases' defined eradication, - "Permanent reduction to zero of the worldwide incidence of infection caused by a specific agent as a result of deliberate efforts; intervention measures are no longer needed". [1]

Only smallpox has so far been eradicated. Smallpox vaccination has been stopped world over and the smallpox virus has been eliminated from the earth, except that a few countries have preserved it in their laboratories. Like smallpox, polio virus too is found only in humans, it is not present in animals. Hence, if for years together, if no case occurs in human beings, the virus has no host for its multiplication and thus the virus may get totally eliminated. That has been the rationale of polio eradication. But this rationale is inadequate. For a disease to qualify for eradication; it must fulfill a few more pre-conditions. The Oxford Textbook of Public Health has summarized these – "To eradicate an infectious disease a combination of factors is required. There must be no known animal reservoir, and disease must result in solid life-long immunity with no long term carrier state. At the same time there can be no sub-clinical manifestation of infection that could result in continued transmission, and case detection must be relatively simple. Above all a highly effective, stable and easily administered vaccine or curative drug

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[1] Quoted by C.Sathyamala, Onkar Mittal, Rajib Dasgupta, Ritu Priya, 'Polio Eradication Initiative in India – Deconstructing the GPIE' – International Journal of Health Services, Vol. 36, Number 2, 2005, P.363

must be available, which, in the case of the vaccine, must confer long term protection." [2] Polio does not meet the last three of these criteria. Yet the Polio Eradication strategy was launched in India from 1995 with the objective of eradicating polio from India by the year 2000.

Three doses of oral polio vaccine were introduced from 1978–79 into the National Immunization programme. This, had reduced the number of reported cases of paralytic polio by 80% - from 24,257 in 1988 to 4,793 in 1994. But in 1995 under the influence of the international agencies, the Polio Eradication strategy was launched by many fold increase in expenses and humanpower deployment on the polio front. Though there was some initial grant from international agencies, this strategy meant more and more expenses for the government either borrowed money or from the budget. Central Government's 2006-07 budget has the following provisions – Pulse polio1,004 crores, routine immunization with other vaccines under the Universal Programme of Immunization 327 crores, tuberculosis control – 184 crores. These allocations are to be assessed in the context of priorities that we have - about 1.5 crore tuberculosis cases and 4 lakh annual tuberculosis deaths as compared to estimated 20,000 cases and less than 500 deaths annually when the Polio Eradication Programme was launched.

Using Polio Vaccine as a supplementary tool in controlling polio was a correct strategy. But joining the international bandwagon for polio eradication by pumping so much resources for it was a wrong decision when other more pressing needs like tuberculosis, malaria, infant and maternal mortality were under-funded.

Despite the huge expenses on polio-eradication because of which our priorities have been distorted, the target of eradicating polio in India by the year 2000 has not been achieved. The targeted deadline has been repeatedly postponed and there is no chance that we can eradicate polio and stop polio vaccination even by 2015.

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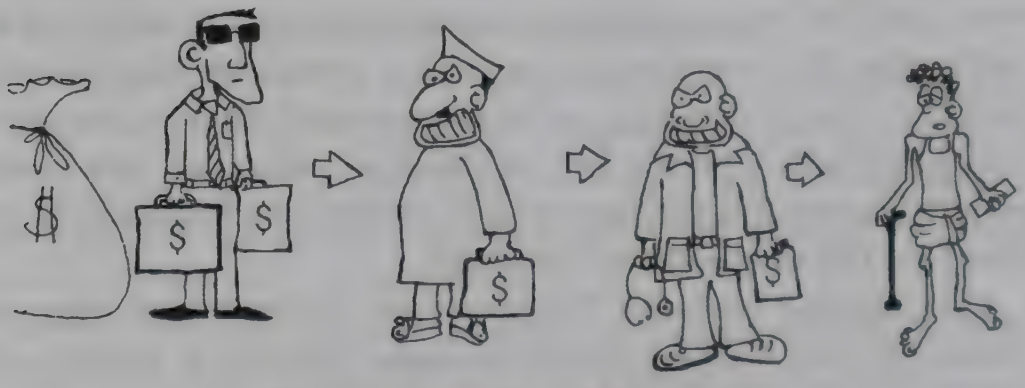
[2] Oxford textbook of Public Health – Fourth Edition, 2005, Editors Roger Detels, James McFwen, Robert Beaglehole and Heizo Tanaka.

If there was no scientific rationale for launching the Global Polio Eradication Initiative, (Polio Eradication in short) why was it launched?

The reason is a combination of misplaced, short-sighted faith in technology and vested interests of the international decision-makers. Poliomyelitis, like many other infectious diseases, is primarily a disease of under/mal-development, of poverty leading to, insanitation, and malnourishment. In developed countries polio and other infectious diseases declined along with improvement in living standards including sanitation. Vaccination and other medical technological interventions have played only a supplementary role. In developing countries, due to poverty, sanitation remains poor. This leads to much wider, easier circulation of the polio virus which in turn causes this disease more frequently amongst the malnourished children. Given this context, in developing countries, improvement in living standards sanitation is the main measure, which would bring down the incidence of infectious diseases. (It must however, be remembered that in case of food and waterborne infections vaccines are a much inferior tool than that in case of air-borne infections. Food and waterborne infections can be much better controlled by controlling the medium of infection – food and water – rather than by protecting the host). But when technology is used as alternative to social progress, an illusion is created that we can overcome diseases primarily with the help of modern technology, this becomes very problematic. It is this narrow, technocratic vision that is to be partly blamed for this misconceived campaign.

The reputed Nelson's Text Book of Pediatrics has also noted *"Undoubtedly, good sanitation explains the virtual eradication of polio as a disease from United States in early 1960s, when only about two third of population was immunized with Salk vaccine, and subsequent absence of circulating wild-type poliovirus in US and Europe. In contrast, poor sanitation and crowding have permitted the continued transmission of polio virus in certain poor countries in Asia and Africa, despite massive global efforts to eradicate polio, in some areas with an average of 12-13 doses of polio vaccine administered to children younger than 5 years of age."* (18th edition, page 1037)

Rulers in the developed countries have a vested interest in eradicating polio in developing countries. Though for many many years, the incidence of polio in developed countries has come down to almost zero, they cannot stop polio vaccination till polio virus is eliminated from the earth. Secondly, the cost of treatment and rehabilitation of whatever paralytic polio cases that occur annually is quite high as cost of institutional health care in these countries is enormous. Polio eradiation would mean an annual saving of 333 million US dollars annually for European Union countries whereas the US will save annually 230 million dollars on vaccine cost alone [3]. It is therefore, worth while for the developed countries to donate a few million dollars initially for the polio – eradication. The experience of the smallpox eradication programme showed that as per the WHO's estimation, the United States - the largest donor for Smallpox Eradication programme - has recouped its entire contribution every 26th day after the eradication[4]. Such donations especially for vaccine – programmes are seen as good philanthropy. But what is sidelined is the fact that primarily it is good investment.



The real cold cold Chain

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[3] Polio Eradication Initiative at what cost, in 'Securing Health for All; dimensions and challenges, ed. Prasad and Sathyamala, P. 269-286

[4] Polio Eradication Initiative at what cost, in 'Securing Health for All; dimensions and challenges, ed. Prasad and Sathyamala, P. 269-286

Apart from the highly technocentric paradigm of vertical programmes, the push by the funders also seems to be a major factor. Jeremy Shiffman has compared disease burden in the developing countries vis-à-vis the annual donations by donor agencies measured in terms of dollars per DALY (Disability Adjusted Life Years). He found that during 1996-2001, tuberculosis and malaria, which contributed 9.10%, 14.3% respectively, to the total burden among 20 diseases, received annual donation 3.82, 6.64 dollars respectively, per DALY for their control programmes. Whereas polio received 1,998 dollars per DALY though it contributed only 0.04% to the disease burden! There is thus mind bogglingly excessive funding to the polio-eradication programme compared to the morbidity load it has generated.[5]

In India, though initially there was some donation through the Rotary International, later on mostly the Indian Government has been paying for this campaign through international loans or through budgetary support. In the 2006-07 budget 1,007 crores have allocated for this

Resurgence of neglected diseases, a relaity

[5] Shiffman Jeremy. Donor funding priorities for communicable disease control in the developing world. Paper presented during the 11th Canadian Conference on International Health, 25th to 27th October 2004; Ottawa, Canada

programme, whereas 383 crores for all other vaccinations together!

Even when most of the even developing countries have been declared as 'Polio – free' and when most of the districts in India have not seen a case of polio for years, doesn't it mean that despite some difficulties and delays, we are close to our goal of eradication!

No! WHO has not rigorously, and consistently followed its own standards of fulfilling the criteria for declaring a country as 'Polio-free'. In 2003, twenty countries that had been declared polio-free by the WHO had not achieved one or more of the indicators for certifications standard[6]. Thus the WHO's claim that only seven countries in the world today have polio may not be factual and has to be taken with a pinch of salt.

As per the WHO report on progress of polio eradication till 2005, (www.polioeradication.org) 22 previously polio-free countries got re-infected since 2003! Countries in which polio reappeared include countries like, - Hispaniola, Albania, Haiti, Netherlands, Philippines, Egypt, Madagascar, Indonesia, Nepal, Bangladesh, Yemen, Indonesia, Namibia. In some of these countries, polio cases reappeared after a gap of many years Add to this polio cases occurring even in the United States due to the oral polio vaccine itself. (More about it a little later). Thus, we are nowhere near the eradication goal.

Why there is reappearance of polio cases in areas declared polio-free? There are four reasons –

i) Even if in a country, or area there is no case of paralytic polio, this does not necessarily mean that there every child has received immunization. For one case of paralytic polio, there are about 1000 sub-clinical cases, i.e., persons with polio infection but no symptoms. These sub-clinical cases continue the chain of replication and transmission of the polio virus.

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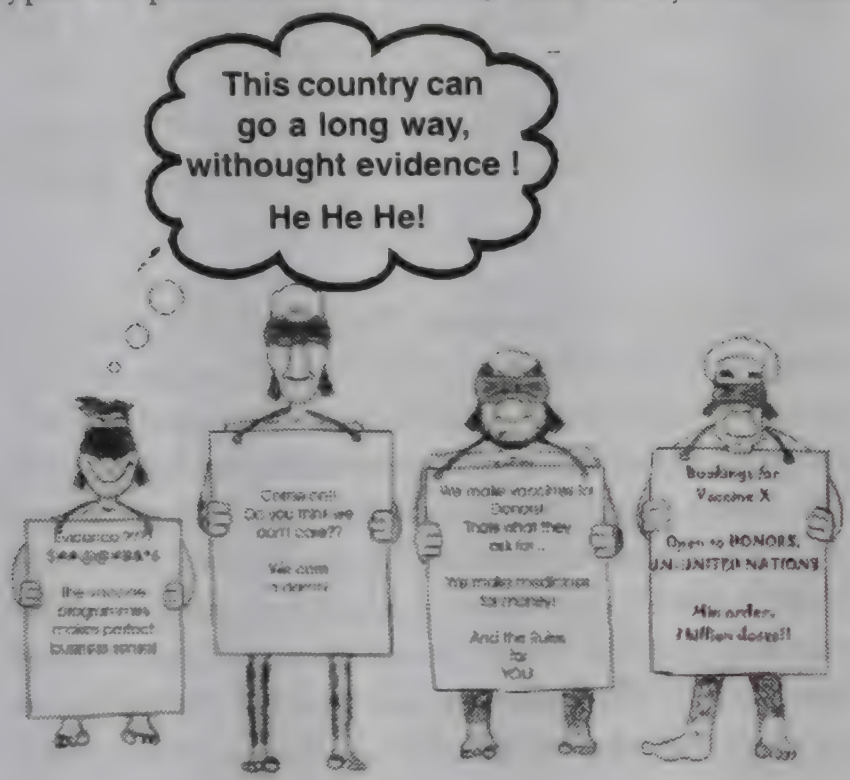
[6] Polio Eradication Initiative at what cost, in 'Securing Health for All; dimensions and challenges, ed. Prasad and Sathyamala, P. 269-286

ii) Out of the children who have received Oral Polio Vaccine, (OPV) not everyone develops immunity against polio. Moreover, the efficacy of OPV in developing countries is known to be lower. Polio virus has three sub-types and hence the OPV also contains three sub-types of attenuated virus (trivalent vaccine). Yet even after repeated doses of this trivalent vaccine, there is no guarantee that every recipient child would acquire resistance due to this vaccine for all the three sub-types of polio virus. There is, thus, always the chance of a pool of



vaccinated but unprotected children!

iii) Some children with less resistance power (immuno-deficient) continue to harbour, multiply and excrete 'wild poliovirus' for prolonged periods. In a world of malnourished children and with the spreading of HIV infection, this phenomenon needs further study.

iv) The vaccine–virus also called as 'Sabin-virus' (named after its inventor scientist Sabin) after its entry into the intestine, reverts back to the virulent virus within a month! This is because the Sabin vaccine

consists of live attenuated virus prepared from the wild virus and has shown the property of mutating back into the virulent virus! This phenomenon of 'reversion' leading to Vaccine Associated Paralytic Polio (VAPP) was discovered in the late fifties[7]. It was taken note of by the WHO[8] and was reconfirmed later by many studies [9, 10]. Even Jacob John, one of the foremost exponents of the polio eradication drive in India has now admitted its significance. "Today, as progress is made towards the goal of global eradication of poliomyelitis attributable to wild polioviruses, all developing countries where OPV is used face the risk of vaccine-associated paralytic poliomyelitis (VAPP). Until recently, awareness of VAPP has been poor and quantitative risk analysis scanty but it is now well known that the continued use of OPV perpetuates the risk of VAPP." [11]

The phenomenon of Vaccine Associated Paralytic Polio (VAPP) is well known. However, it is not clear whether VAPP is due to the vulnerability of some children because of which even attenuated vaccine virus causes paralytic polio (host factor) or because the 'reverted virus' is virulent enough to cause paralytic polio in healthy children (agent factor) or because of combination of both these two factors. Whatever may be the mechanism, it is very clear that a few cases of paralytic polio are bound to occur as long as Oral Polio Vaccine is use. These cases of VAPP mean multiplication of the virulent polio virus in the intestines of these patients and their spread to others. The WHO report on Polio

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[7] DANE: Vaccination Against Poliomyelitis with Live Virus Vaccines. BMJ, 1957, January 12, PP 59-65

[8] WHO – TRS 1958, No. 145: Expert Committee on Poliomyelitis

[9] Melnick et al. 'Studies of the immunogenicity, communicability and genetic stability of oral polio vaccine administered during the winter' American Journal of Epidemiology, 1967, Vol: 86, 112-135

[10] Guillot et al. Point Mutations Involved in The Attenuation / Neurovirulence Alternation in Type 1 and 2 Oral Polio Vaccine Strains Detected by Site Specific Polymerase Chain Reaction. Vaccine – 1994 Vol.12, No. 6, 503

[11] Jacob John T.End-Stage Challenges Vaccine-associated paralytic poliomyelitis, Bulletin of the World Health Organization | January 2004, 82 (1)

Eradication mentioned above also very clearly mentions the issue of VAPP. It says "ability of Sabin vaccine viruses to mutate and acquire greater transmissibility and neurovirulence necessitates an eventual end to the use of OPV. While the current risk posed by wild polioviruses remains far greater than the risk of vaccine-derived polioviruses (VDPVs), the number of wild viruses is rapidly decreasing; and as long as OPV use continues, the threat of VDPV will persist. A threat, if not addressed, could negate the eventual achievements of polio eradication. It is for this reason that OPV is considered incompatible with a polio-free world -----" (page 26)

Given all these four factors together, there is no way we can eradicate the polio – virus through vaccination alone, at least as long as we use the Oral Polio Vaccine.

In Japan, where wild viruses were eliminated many years ago, it was found that river and sewage contained vaccine-derived viruses shed by vaccinated children. (Yoshida H, Prevalence of vaccine-derived polioviruses in the environment, J Gen Virol 2002; 83: 1107 -1111)

Even the criterion for declaring a country 'polio free' is problematic. If no polio case occurs for three consecutive years in a country, it is declared polio free. This is arbitrary. because Polio Viruses may be circulating in the environment even if there is no polio case. It may be noted that the Enterovirus Research Centre, (ICMR), Mumbai, had isolated type 2 polio virus after 3 years of freedom from a case of paralytic polio. (Deshpande J. M. Detection of MEF1 laboratory reference strain of poliovirus type 2 in children with poliomyelitis in India in 2002 & 2003. IJMR, 118, December 2003, pp217-223).

We may not have reached the goal of zero polio cases, but haven't we achieved the drastic reduction of paralytic polio cases from around 5000 per year in 1994, before the launch of the Eradication Drive, to only 66 cases in the year 2005?

These figures are misleading because the figures of polio-incidence in the eighties are a gross over estimation. Secondly, the drastic reduction shown during last 6 years is partly due to the change in definition of a polio case! Let us unravel these misleading statistics! – International experience had told us that only a proportion of cases of Acute Flaccid

Paralysis (AFP) are due to the Polio Virus and the rest are due to other viruses. The Latin American experience showed that only 7% (349 out of 4986 AFP) of the AFP cases during 1989 to1991 were due to polio.[12] In Vietnam out of 22 AFP cases, only one had wild polio virus in the stool sample[13]. But in India, while estimating the number of polio cases, it was assumed that all cases of AFP were due to the polio virus. From 1998, advanced laboratory facilities were set up in India to monitor the progress of the Polio Eradication Campaign. As seen from the data in Table 1 for 1998, 1999 of results of laboratory culture of stools of all cases of AFP that only about 10- 20% of AFP cases were due to the Wild Polio Virus!

Table-1 : Acute Flaccid Paralysis Cases in India, 1998 -2003[14]

Year	AFP cases	Wild polio cases. confirmed	Wild polio cases, as % of AFP case	Non-polio AFP cases
1997	3,047			
1998	9,461	1,934	20.4	7,527
1999	9,587	1,126	11.8	8,461
2000	8,103	265	3.3	7,838
2001	7,470	268	3.6	7,202
2002	9,705	1,600	16.5	8,105
2003	8,505	225	2.7	8,280

The claim of 97% reduction in polio cases in India is partly due to terminological jugglery. Up to 1996 all reported cases of acute limb paralysis were labeled as polio. From 1997 onwards, such case is labeled as polio only after thorough investigations. As a result, for example in

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[12] Dietz, J. Andrus, S. Cochi, et al, Epidemiology and clinical characteristics of Acute Flaccid Paralysis associated with Non-polio Enteroviruses: the experience in the Americas, Bulletin WHO, 1995, 73 (5), 597-603.

[13] Solomon, Racheel Kneen et al, Poliomyelitis – like illness due to Japanese Encephalitis virus, The Lancet, Vol. 351, April 11, 1998, 1094-1097.

[14] Table reproduced from Sathya et al, op.cit, P. 367.

1999 only 12 % of such cases were labeled as polio whereas earlier *all* such paralysis cases were labeled as polio!

Further, while interpreting the figures in table 1, the following needs to be kept in mind. In the year 2000, the National Polio Surveillance Project (NPSP), the official body which monitors the progress of polio eradication in India, created a category called "compatible cases". Before that all the AFP cases, where stool sample was not collected within 14 days, were followed up for residual paralyses and those cases which were found to have residual paralyses after 60 days, or died or lost to follow-up were included as confirmed cases. However after the year 2000, records of all such cases were referred to the National Expert Review Committee (NERC) which decided to put some of these cases in the compatible category, meaning that these cases are not confirmed Polio cases but are compatible with the category of polio cases. This new method of classification could be one of the possible causes of sudden drop of Wild Polio Virus cases from the year 2000 onwards. The criteria on which the NERC arrived at the decision to put certain cases in compatible category, has not been given by NPSP.

Thus, the number of polio cases in India in 1994 were not 5,000, but were 10 to 20% of this figure, i.e., between 500 to 1,000.

The definition of 'polio case' has been changed from 1998. From 1998, only those AFP cases in which stool sample shows Wild PolioViruses on culture in the laboratory are called polio cases. The drastic reduction in polio cases from 1994 to 2005 is thus more due to this change in the definition. Secondly, in India not all cases of AFP have been fully followed or properly investigated. Some of these inadequately investigated cases may be due to polio virus, but are not counted as such. Hence, this low figure of only 225 and 66 polio cases in 2003 and 2005 are somewhat misleading.

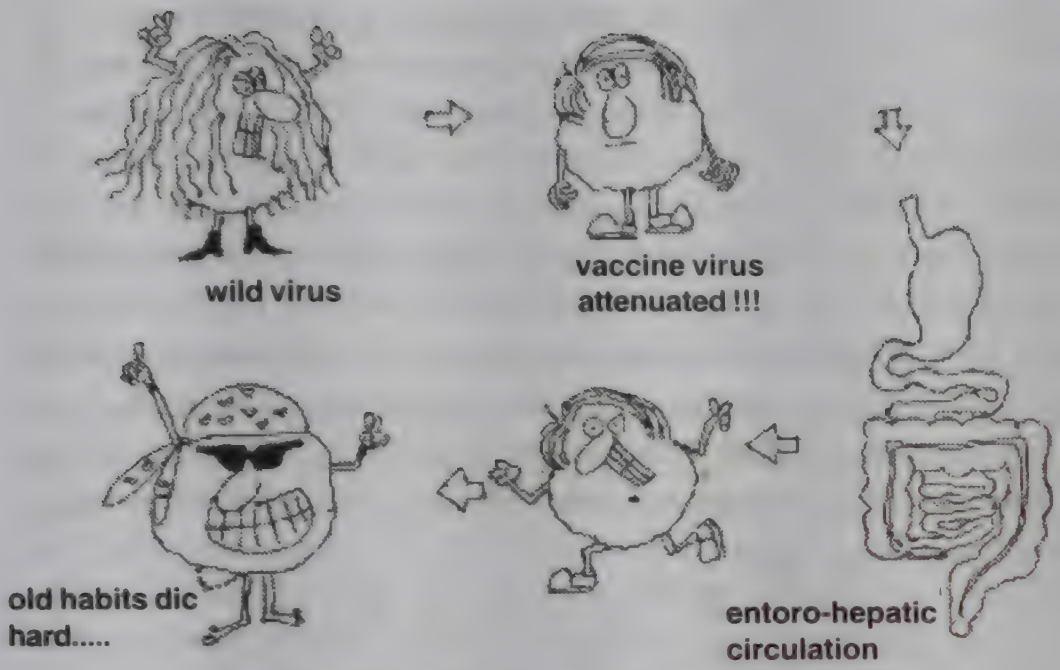
When we talk about polio cases, now we should also include 'vaccine virus cases' in this count and not only Wild Polio Virus (WPV) cases. ('Vaccine virus cases' means cases in which vaccine virus has been isolated when stool sample is collected within 14 days of the onset of the paralytic attack.) As seen from Table 2, while WPV cases which

were confirmed in the laboratory decreased from 1,934 to 66 during 1998 to 2005., But there has been a spurt in 2006 with more than 400 cases officially admitted by November! 'Vaccine Virus cases' confirmed in the laboratories increased from 500 to 1,645 during 2002 to 2005.! Thus total number of paralytic polio cases in (natural and vaccine–associated) India has fallen from 2,100 to 1,710 during 2002 to 2005, i.e., merely by 19%!

If we keep aside vaccine-associated cases and focus only on 'natural' cases of polio, during eight years of the Eradication Campaign from 1998 to 2005, there has been a 97% reduction in the natural polio cases. Compare this with the reduction of 80% of polio cases (from 24,257 cases in 1988 to 4,793 in 1994) during seven years of routine immunization prior to the Eradication drive. So the reduction of even WPV cases specially due to the 'Eradication Programme' is not very substantial given the huge, more than ten times increase in the money, and humanpower spent on the 'Eradication Programme'!

As the incidence of natural polio cases declines, it is expected that the proportion of Vaccine Associated cases would automatically increase. Is it something so very alarming?

It is not merely that the proportion of 'Vaccine Virus Cases' has increased four fold. It will be seen from table 2 that the total number of AFP cases have jumped from 8,505 in 2003 to 27,050 in 2005 and 'vaccine virus cases' have increased from 500 in 2002 to 1,641 in 2005. It may be noted that the NPSP web site www.npspindia.org does not give clear figures about VAPP. It gives figures about 'vaccine virus cases' i.e. number of AFP cases in which vaccine virus has been isolated when stool sample is collected within 14 days of the onset of the paralytic attack. It is not clear how many of these have residual paralysis after a 60 day follow up and hence confirmed as polio cases. The data for the vaccine virus cases are available to us only since the year 2002.. The NPSP does not say anything about whether these cases are of VAPP or not. The data have been constructed from the tables on virological analysis of the polio positive cases given by the NPSP in its regular bulletins.



Vaccine induced paralysis -life cycle

Table-2 : The Status of Polio Eradication in India (from 1997 -Nov.2006)[15]

Year	Total AFP	WPV cases	Vaccine-Virus cases	Total polio cases
1997	3,047			
1998	9,461	1,934		
1999	9,587	1,126		
2000	8,103	265		
2001	7,470	268		
2002	9,705	1,600	500	2,100
2003	8,505	225	474	699
2004	13,274	134	894	1,028
2005	27,050	66	1,641	1,707
2006	28,939	583	1,218	1,801

[15] Onkar Mittal, C. Sathyamala. Global Polio Eradication Initiative in India 1995 – 200, Background information Note prepared for the IMA consultative meeting on 4th May 06, New Delhi, Table 1, P.8. This table is based on data from www.npsindia.org.

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Obsessed with the idea of vaccine induced polio-eradication, the authorities have been pushing more and more doses of OPV into the population, unmindful of the fact the more the OPV doses, the more are the number of polio cases. Some of the AFP cases categorized as 'non-polio' are likely to be polio cases as many cases of AFP are not adequately followed. Complicated classification of these 'non-polio' AFP cases is offered by the authorities to show that they are indeed not due to polio. This official view has been questioned[16]. We cannot go here into this technical, and complex issue. But suffice it to say here that this steep rise in vaccine induced polio cases as well as in AFP cases as the Polio Eradication drive is pushed more and more rigorously, is a cause of great concern.

Deep in the ponds of polio drops..

It should be noted that though the incidence of OPV induced polio is less in India compared to that in the West, it is still considerable in view of the repeated rounds of OPV administered for millions of children – 1 case per 2 million doses for the first dose; 1 case per 12 million doses for subsequent doses; 1 case per 4 million doses overall [17].

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[16] Onkar Mittal, C. Sathyamala, op.cit, P.

[17] Yash Paul, Polio Eradication : Experts have misled us, Medical Veritas 3 (2006) pg. 781-785, P. 784

The Government has executed and has tried its best to popularize the 'Pulse Polio' programme! Doesn't it have any advantage? Wouldn't it help to eradicate polio?

Pulse polio programme means giving oral polio vaccine to all under five children on the same day throughout the country. The idea is - if the vaccine virus is introduced simultaneously into the intestine of all the children it will be replicated, excreted by all children and thus it will outnumber the Wild Polio Virus that is being excreted by a few children. Vaccine virus will thus 'flush out' and replace the WPV. Immunity which is simultaneously developed in the intestine by all the vaccinated children would mean that the WPV will not have any site left for its multiplication.

It should be noted that in India, the government is not only using the 'pulse' technique of simultaneous administration of the vaccine to every child under five, but if a case occurs, additional pulse round is also executed. Added to this, in some areas, are the mop-up round of Pulse Polio. These extra rounds are problematic as many children receive up to 10 and even twenty doses of polio vaccine through these different rounds. More the doses of OPV, more are the cases of vaccine induced polio. The steep rise of vaccine induced polio cases is because of these extra rounds. In Cuba, for years together, there are only two rounds of pulse polio in a year. This is quite productive, efficacious use of the OPV. But in India, the concerned authorities are so obsessed with the idea of immediate polio eradication, that even if one case of polio occurs, all the under five children in the entire State are given an additional dose of OPV.

The obsession with Pulse Polio Programme has adversely affected the functioning of the already tottering public health care in India. Even immunization coverage of other vaccines has declined from 54% to 48% during 1998 to 2003 [(18)]. According to the National Family Health Survey III, in Maharashtra this coverage has declined from 78.4% to 58.8% during 1998-99 to 2005-6!

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[18]India Summary Report, Reproductive and Child Health, DistrictLevel Household Survey 2002-04 & Fcility Survey 2003. IIPS, 2006, page 9.

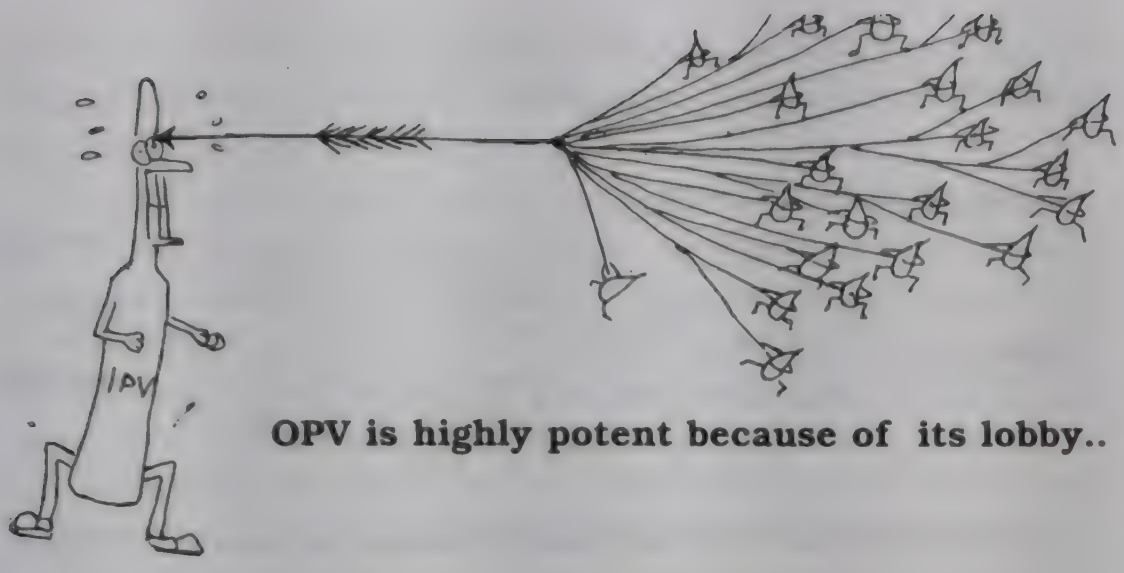
The Pulse Polio technique has a certain advance over conventional, routine oral polio vaccination. However, adoption of this technique means negation of one important claimed advantage of OPV. - It was claimed all these years that one of the distinct advantages of the OPV is the phenomenon of 'herd immunity'. It was claimed that in case of OPV, even if we are able to give the vaccine to only 60 to 70% of the children, the rest too get protected. This is because the vaccine virus replicates in the intestines of the vaccines and spreads to other, non vaccinated children. Whether this herd immunity occurred in reality has been questioned. But the point to be noted here is - in pulse polio, the aim is to vaccinate simultaneously each and every child, which essentially implies loosing one important claimed advantage of OPV.

If OPV causes vaccine – induced polio in a few children, why was it chosen in India in the first place? Weren't there an alternative?

Injectable polio vaccine invented by Salk was available. But unlike OPV it does not produce any immunity in the intestine, but produces immunity only in the blood. Thus, after vaccination, polio viruses can grow in the intestine, though they can not reach the nerves. Secondly, it is far more costy than OPV.(currently a hundred times!) It was also argued then that OPV is very easy to administer to children, whereas injectable salk vaccine requires trained medical personnel for its administration. Despite these advantages of OPV, it was found that in tropical countries including India, its efficacy is much lower. Yet surprisingly, Indian health authorities chose OPV for the National Immunization Programme. Dr. Pushpa Bhargava, the renowned scientist in the Department of Biotechnology has shared a very revealing, story in a bold article in the Hindu [19].

In the early eighties, the WHO in its 'Review of Current Status of Oral and Inactivated Poliomyelitis Vaccine' stated, – "Serological evidence suggests that OPVs are not as effective in warm as in temperate

[19] Bhargav Pushpa, Fighting the Polio Virus, the Hind, 12th December 1999, Sunday.



OPV is highly potent because of its lobby..

climates" and "it must be stressed that the results obtained in some developing countries using OPV are not as good as could be hoped!" Indian researchers had also come to the same conclusion. In a meeting in March 1988, experts including Dr. Jacob John recommended that India should use IPV instead of OPV and that indigenous production of IPV should be aimed at, at the earliest. A plan was prepared to set up an IPV plant at Guragaon and there was a possibility of converting the OPV plant at Bulandshahr into an IPV plant. But mysteriously, the WHO suggested that India should use OPV in the National Programme, and under the influence of the WHO, the authorities decided to choose OPV. Dr. Bhargava tried to pursue the matter with different authorities but in vain. The question is - why did this mysterious shift take place? Why is that capacity for indigenous production of the polio vaccine was thwarted? Had manufacturer of OPV (Pfizer- an MNC) in the US, any role in this? Why was it that the Indian Vaccine Corporation Ltd. Set-up with an expenditure of Rs. 50 crores was side-tracked and wasted? Whatever and whosoever may be the behind the scene moves, the fact remains that we were saddled with a not so effective and not so safe vaccine with the help of which an eradication programme was launched!

Social Economic Political and Cultural issues to be dealt with strongly

Social determinants to health
Combating disease with immunization as a component

The story by Dr. Bhargava is corroborated by Dr. Jacob John's remark in a paper in the WHO bulletin – "When the Expanded Programme on Immunization was established and oral poliovirus vaccine (OPV) was introduced for developing countries to use exclusively, national leaders of public health had no opportunity to make an informed choice between OPV and the inactivated poliovirus vaccine (IPV)" [(20)].

What has been the experience of developed countries about the use of the Polio Vaccine?

Right from the beginning there has been a tussle between OPV and IPV invented by Sabin and Salk, respectively. In the US, polio immunization started with Salk vaccine. But because of some manufacturing defect, it produced a small epidemic in 1955 in California, hence fell into disrepute and was discarded in the US; from 1956, OPV was launched. Thanks to the perseverance of Salk, improvements in the manufacturing of IPV were made and thanks to the Public sector

[20] Jacob John, op. cit.

manufacturer in the Netherlands - Rijks Instituut voor Volksgezondheid (RIV) that IPV production continued without regard to prospects of profitability. [21]

By 1988, it was clear that 'enhanced Injectable Polio Vaccine (IPV)'would be more effective in tropical countries and Finland, Netherlands, Sweden had brought down the polio cases to zero with the use of IPV. Then why is it that the WHO continued to recommend OPV for third world countries? Was there any influence of the US multinational Pfizer on the WHO's decision making process? IPV was much costlier than OPV. But was it possible to bring down the cost by manufacturing it in India given the fact that IPV was manufactured in the Netherlands with the help of kidney cells of monkeys imported from India!

How can WHO give a wrong advice? Is it failure of expertise or influence of vested interests?

Perhaps a combination of both. WHO fostered the polio eradication programme when it should have known that this is unattainable. The phenomenon of reversion of vaccine virus into virulent virus; the relative inefficacy of OPV in tropical climate --- all this was known. Yet the Global Polio Eradication Initiative (GPEI) was launched and OPV was recommended for India. Now the international authorities have somewhere realized that eradication of polio and hence cessation of polio vaccination is not possible. Without squarely admitting its mistake, WHO has quietly changed the objective of the polio eradication drive to that of 'polio elimination'; which means no cases of polio, but polio vaccination would continue as the polio virus has not been eradicated. WHO has now come up with the ridiculous "Post-eradication strategy" (a contradictory term!) for vaccination in which it is left to individual countries to decide whether they would give oral, or injectable polio vaccine in the 'post–eradication' phase!

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[21] Stuart S. Blume, Lock in, the state and vaccine development: lessons from the history of the polio vaccines, Research Policy xxx (2005) xxx–xxx, pp. 1-15

That the GPEI was based on manipulation of not only concepts but also of statistics is shown by the way WHO exaggerated the problem of polio. As pointed out earlier, all cases of limb-paralysis or lameness in children were counted as polio, when only a small proportion of them is known to be due to polio. Secondly, while in 1988, there were about 35,000 cases of paralytic polio reported world wide, WHO experts argued that since there is gross under reporting of such cases, the estimated incidence is 10 times more than this figure! After a few years, in 2004, in the Geneva Declaration for the Eradication of Poliomyelitis; this figure of 3.5 lakh estimated cases of poliomyelitis was quietly converted into reported cases. In the document presented to the 57th World Health Assembly in May 2004, WHO experts' statement says that polio is responsible for "paralyzing more than 3,500,00 children" [22]. So much for the intellectual integrity of these experts!

Independent experts, commentators in India have been pointing out the basic problems with the Polio Eradication strategy. [23, 24,25, 26, 27,28] But no attention has been paid to these dissenting voices.

Now what should be done henceforth?

The 10th Five Year Plan document had said, ---"The medical goal of polio eradication is to prevent paralytic illness due to polio viruses by elimination of wild polio virus so that children need not be immunized

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[22] Sathyamala, et al, op. cit.

[23] Memorandum on Polio Eradication Initiative in India Submitted to the World Health Organization, UNICEF, and the Government of India, on 7 April 2004, The World Health Day.

[24] The mirage of polio eradication, Phadke Anant, Kale Ashok, (letter), NMJI, Vol. 5, no 4, p. 282.

[25] Deodhar-N.S. Poliomyelitis Eradication: An impracticable task and Pulse Polio Program can never do it, Pune, School of Health Sciences. University of Poona, September, 2003:

[26] Debar Banerjii, Global Program of Polio Eradication in India-The study commissioned by West Bengal Voluntary Health Association.

[27] Kale Ashok, Is Polio Eradication Really Possible? Presentation during the Seminar in the School of Health Sciences. University of Poona, September, 2003

[28] Yash Paul, Polio Eradication : Experts have misled us, op. cit.

perpetually". Authorities have to now openly admit that this is not possible. We must shift back from the polio eradication mode to the polio control mode. Let it be clearly admitted that vaccination is only supplementary to improvement in living standards including sanitation, nutrition.

The following needs to be done –

1. A phased withdrawal and closure of the pulse polio programme and the reintegration of polio immunization into the Universal Immunization Programme.

2. Acknowledged that the failure of polio-eradication is not due to lack of efforts by the health staff or because of lack of adequate co-operation from the citizens but due to the basic flaw in the conceptualization and design of the programme.

3. The data about Vaccine Associated Paralytic Polio (VAPP) must be made available in a transparent manner and all VAPP cases should be fully rehabilitated and compensated for sacrificing their limbs involuntarily for the (mistaken) goal of polio-eradication.

4. A comprehensive epidemiologic investigation into the cases of AFP, to know the exact cases and their nature, the reason for their increasing incidence, (and to provide appropriate treatment and rehabilitation).

5. To stop the occurrence of vaccine induced polio cases, the option of shifting to Injectable Polio Vaccine (IPV) should be considered again by taking into account all the pros and cons. If at all a decision is made to use IPV, it's very high cost as of today, can be brought down by opening the manufacturing of IPV in a Public Sector enterprise. (if the Private Sector too is to be involved, it should be under price – control.) It has been estimated that "By reducing the per-dose cost of IPV from US$ 2.00 to US$ 0.50, the total costs of using IPV in low-income countries over the period 2005–20 will be nearly equivalent to continuing OPV use with periodic supplemental immunizations during this same period." [29].

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[29] Nalinee Sangrujee,1 Victor M. Cáceres,2 & Stephen L. Cochi2, Cost analysis of post-polio certification immunization policies, Bulletin of the WHO, January 2004.

6. Enhance the budget and programme for Public Sanitation many times. This will help to control all food and water borne diseases and not only polio.

7. An independent commission be set-up which will investigate why this decision of launching Polio-Eradication Programme with OPV was taken and draw necessary lessons for the future.

The example of polio eradication shows that WHO's expertise cannot be the last word and Indian experts have to apply their own mind and thinking critically to safeguard the interests of the Indian people. WHO may get influenced by powerful interests and hence independent critical expertise from third world countries should have a place in the policy making of WHO.

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(I am thankful to various participants of the Jan Swasthya Abhiyan Workshop in Hyderabad on 14th-15th July 06 for giving suggestions for improvement in the draft that was circulated for this workshop; Dr. C. Sathyamala of the Medico Friend Circle and Dr. N.S. Deodhar for their comments & suggestions. The author alone is responsible for the contents and for any lacunae that may have remained.)

3. Universal Hepatitis B Vaccination

HepatitisB vaccination is a classic example of how a particular technological intervention is systematically foisted on the people by the powerful medico-industrial vested interests when there is no scientific rational for such a use. Lets see how this is being systematically carried out.

What is this infection? It is said that it is far more dangerous to the general public than AIDS. Is this true?

No! Hepatitis B infection spreads much more rapidly than AIDS, but is of course far far less dangerous than AIDS. Let us go into some details to know what are dangers of hep B infection. This will help us to decide about the hepatitis B vaccine.

Hepatitis means inflammation of the liver. It is sometimes caused by germs, including viruses or sometimes by toxic chemicals like alcohol. When it is caused by one of the five types of hepatitis- viruses - A,B,C,D,E, These are broadly called 'Viral hepatitis'. Out of these five types, type A, D and E spread from the infected person to others through faeco-oral route. This means if the viruses in the faeces of the infected persons get mixed up in water or food for others, through flies or hands or through leakage of sewage into drinking water sources, other people get this infection. These viruses grow in the liver, cause inflammation of liver. This liver infection causes various symptoms like lack of appetite, nausea, fever, abdominal pain, jaundice, weakness, itching etc. (all these symptoms may not be present in each patient). This illness called as infective hepatitis in medical jargon is generally known as jaundice by lay-people, though jaundice is just one of the outward manifestations of this temporary liver infections. In most cases the patient recovers on its own in 3-4 weeks, as the invading virus is eliminated by the body's defence mechanism. No medicine is available to kill these viruses. Doctors can give medicines only to reduce symptoms like fever, itching etc. Very rarely the infection of liver is very severe and may cause liver failure, which may lead to death. In some cases, especially in

small children, infective hepatitis occurs without causing any jaundice and this illness passes off as some minor febrile illness.

Virus subtype B and C are of a different nature. Like the AIDS virus, they spread mostly through infected blood from the infected persons to others or through sexual relations and are far more dangerous than subtypes A,D,E. They many a times do not cause jaundice, merely cause a minor febrile illness and in majority of cases recover completely on their own. However, compared to Hepatitis-A,D,E a much higher proportion of persons infected with subtype B,C become serious and hence much higher proportion of such patients die due to this blood-borne hepatitis. Moreover, a few of persons with infection continue to remain infected with this virus for a long period. Amongst the adults who get infected with hepatitis-B, only about 10% develop this chronic infection, whereas amongst infants who get the about 90% get this chronic infection. Many of these chronically infected persons eliminate this virus in a few years and hence are out of danger. But some continue to harbour it for a very long time, even life long! Amongst these 'long term carriers' about 10% develop a serious liver disease called cirrhosis and after 20-30 years of chronic infection, some develop liver cancer.

Thus overall this blood borne is far more dangerous than hepatitis A, D, E. However in India only 2% to 3% of population has chronic hepatitis B infection.

This blood borne infection is not only more dangerous than the oral hepatitis infection; it is very highly infectious i.e. it spreads very easily to others. It spreads not only through blood, but also through other body fluids mainly through semen during sexual intercourse or even saliva. Thus if a child with infection bites his friend in a scuffle the other child can get this infection through the saliva of the infected child. infection spreads exactly via the same route as the HIV virus, but it is 100 times more infectious than the HIV virus. (But at the same time we should remember that HIV virus gets killed within seconds if an infected needle, but in case of hep B virus syringe must be boiled for 20 minutes!)

This fact that Hep-B virus is far more infectious than the HIV virus is misused by some vested interests to make misleading statements that

Comparative Expected Deaths due to HIV and HBV

Virus	Population Affected	Deaths
HIV	5 million	5 million
HBV	10 million	50 thousand

is far more dangerous than HIV virus. Common cold caused by a virus is extremely infectious, spreads than the HIV virus. This does not make common cold a more important Public Health problem than AIDS. How dangerous an infection is and how fast does it spread - both are important. In case of HIV, it is estimated that in 2006, in India about 5 million have been infected. Since no medicine can eliminate HIV infection and since all those who get AIDS would ultimately die due to AIDS, all these 5 million people are likely to die of AIDS (unless some cure is found). Compared to this, about 10 million people (1%) of the population) have chronic infection and not more than 5% of them will die due to liver cirrhosis or liver cancer.

It will be clear that some people are unnecessarily creating a scare about infection by highly exaggerating the dangers of infection. Because of this scare, lay people are much more ready to take the vaccine, though they may not exactly afford it.

In cities like Mumbai, there were banners pledging freeing the city of jaundice through this vaccination. Many people got the impression that the epidemic of jaundice that oft and on affect people would be eliminated through this vaccination and hence many get this vaccine with this expectation. But the above information would make it clear that this vaccination in no way would prevent the usual, familiar jaundice caused by A,D,E viruses. Thus, people from all backgrounds continue to be mislead and cheated!

Does this mean that nobody needs to take this vaccine?

Some people are much more likely to get infection than the ordinary people. They should certainly get the vaccine -

1. Doctors and other health care professionals, especially those who handle blood, urine etc. of patients. For example, hospital staff, especially those involved in surgical, maternity work; health workers in blood banks, pathological laboratories etc.

2. Patients with such diseases, which require repeated blood transfusions like patients who get a disease called thallasaemia. Though it legally mandatory that all blood banks must test all their blood bottles for infection, there are certain loopholes, because of which it is can not be ensured that all blood bottles are free of virus.

3. Patients who have to undergo repeated dialysis. This is because the dialysis machine is used by other patients, some of whom may have infection and it is virtually impossible to always completely eliminate contamination of this machine.

4. Newborn babies of those mothers who have infection. About 3% of Indian mothers have infection, and their babies are highly likely to get this infection during birth.

5. Spouses / sexual partners of those who have chronic infection

6. Commercial sex workers or those who have multiple sexual partners.

MANDATORY VACCINATION FOR:

- HEALTH CARE PROFESSIONALS.
- PATIENTS WHO REQUIRE FREQUENT BLOOD TRANSFUSIONS.
- CHILD OF AN INFECTED MOTHER (WITH IN 48 HOURS OF BIRTH)
- SPOUSE OR PARTNER OF AN HBV POSITIVE PERSON.
- COMMERCIAL SEX WORKERS/PERSON IN UNSAFE SEXUAL RELATIONS

Doctors now days advise that children should be given this vaccination as a matter of routine along with other routinely given vaccines. Isn't it a good advice?

Though the chances of a child getting serious liver disease due to infection care very low, those who can easily afford this vaccine can give it to their children. But do not feel guilty if you cannot afford it. About 10 years back when this vaccination for children was started, the cost of this vaccine was Rs. 500 per child for three doses. Now it has come down to less than 50 Rs. per child.

There is one group of children who should certainly get this vaccine. As mentioned earlier, new born babies of mothers who have infection should get this vaccine. For this purpose, firstly, all mothers' blood must be tested during pregnancy for infection. About 3% would be found to be have this infection. Their babies should receive the hep-B vaccine within 48 hours of birth as this infection is passed on to them during birth.

Some schools, some swimming pool indirectly make it compulsory to have hepatitis- B infection. This compulsion is certainly not justified.

The government is planning to give vaccine to all infants by including it in the routine vaccination programme, along with other usual vaccines like BCG, Polio, triple vaccine etc. Isn't this a welcome step?

In our families, we decide our priorities about on which items we would spend our money. Similarly, public health fund must be spent according to the Public Health priorities. There are so many diseases and other health problems, which require public health measures. There are killer infections like diarrhoeas, pneumonias, tuberculosis, malaria, HIV etc.etc; gynaecological and maternal problems; malnourishment; diseases due to addictions like tobacco and alcohol; accidents and occupational health problems etc.etc. Amongst these money spent on vaccine preventable diseases is most efficacious way of spending public funds. But this does not mean that whichever safe and effective vaccines are available, all are to be given. We have good vaccines on hepatitis A, Haemophilus Influenzae (a very serious illness) chicken pox etc. etc. Not all these vaccines need to be and can be given to all the people.

What proportion of people get affected; what is the consequence of this infection; what is the safety and efficacy of the vaccine (some vaccines induce resistance to only a smaller proportion of the vaccinated people i.e. are less efficacious); what are funds, trained human power, facilities available (if refrigerators are needed to store this vaccines — all such factors have to be taken into account to make a decision. By vaccination how many lives would be saved by preventing deaths? How many years of illness would be avoided? At what cost? These questions must be asked. The cost of the saving one-year of life by using each of these vaccines should be estimated and should be compared with that of the currently used vaccines like BCG, Polio, Measles etc. No such exercise has been done by any of those who have been advocating the hepatitis-B vaccination of all children.

The WHO has advised a framework for taking decision-making on new vaccines[1]

The following set of questions is suggested in this framework:

1. Is the disease a public health problem?
2. Is immunization the best control strategy for this disease?
3. Is the immunization programme working well enough to add a vaccine?
4. What will be the net impact of the vaccine?
5. Is the vaccine a good investment?
6. How will the vaccine be funded?
7. How will the addition of the new vaccine be implemented?

The WHO had also given a guideline that countries in which less than 2% of the population has chronic hepatitis-B infection should take up a 'selective' vaccination programme.[2] This means only high-risk

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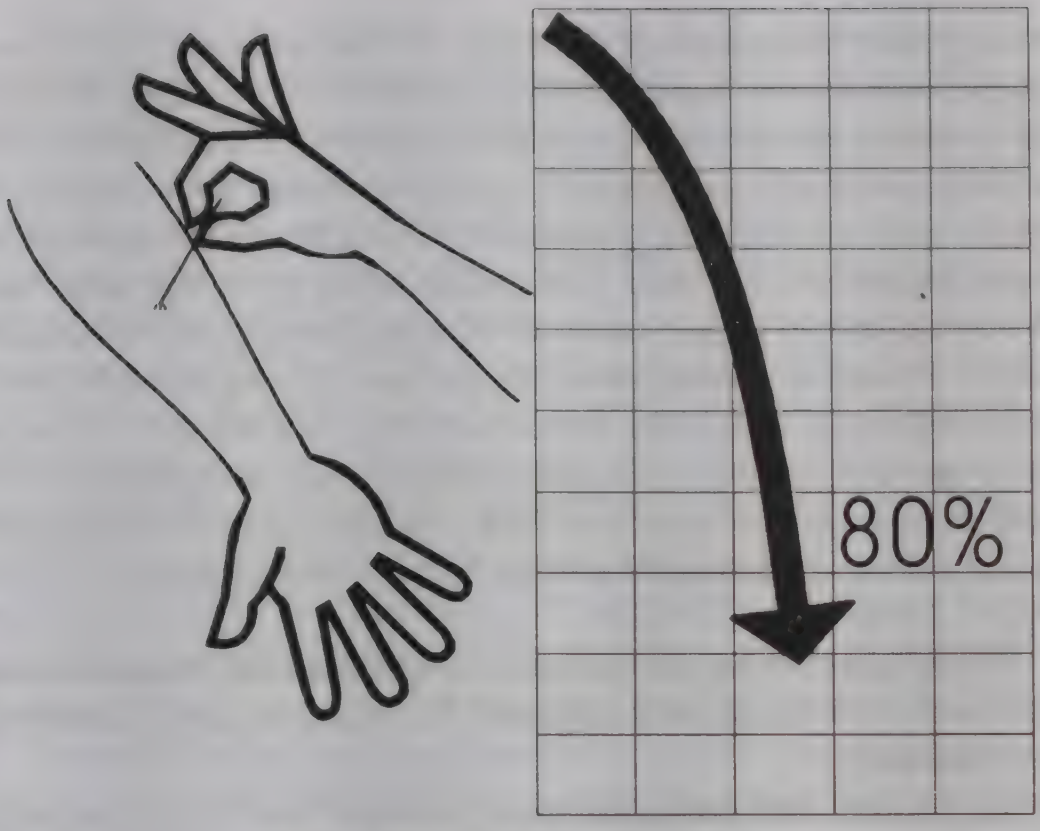
[1] Assessing new Vaccines for National Immunization Programmes – A Framework to assist decision-makers – Immunization Focus World Health Organisation, Regional Office for the Western Pacific, Manila, 2000

[2] Ghendon Y. WHO Strategy for the global diminution of new cases of hepatitis B. Vaccine, 1990, 8: S 129 133



Intradermal Vaccination
Reduces Vaccine Requirement by 80%

groups (mentioned earlier) be given hepatitis-B vaccine. The largest amongst them is newborns of mother who have chronic hepatitis-B infection. Accordingly, countries like Japan, U.K., Netherlands, have instituted the 'selective' programme [3,4,5] even though they can afford to vaccinate all newborns. In India financial resources is a problem. When the Indian Academy of Paediatrics the body of child-specialist,

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[3] Kusuya Nishioka, Transfusion Transmitted Diseases, in Hepatitis B in India, K. Sarin, A.K. Singhal(cds.), CBS publisher, 1st Edition, Page 223.

[4] Department of Health, Welsh Office, Scottish office Home & Health Department, DHSS (Northern Ireland). Immunization against infectious disease. London: HMSO, 1992: 110-19.

[5] Grosheide PM et al. National Hepatitis B Steering Committee, Programme for preventing perinatal hepatitis B infection through screening of pregnant women and immunization of infants of infected mothers in the Netherlands, 1989-92. BMJ 1995; 311: 1200-2.

recommended vaccination of all infants, the vaccine- price for 3 doses of hepatitis-B vaccine was Rs. 200/- per child! Even assuming that for a bulk purchase, the vaccine-price could be half of the commercial price, the vaccine-cost of vaccinating 25 million newborns every year would have been 250 crore rupees! This was double the budget for tuberculosis control programme (TB kills 5 lac Indians every year!) and more than the vaccine cost of all the other six vaccines being given to children under the National Immunization Programme. During last 8-10 years, the vaccine prices have come down drastically- now the govt. should be able to get this vaccine in its bulk purchase at Rs. 20 per child for 3 doses! Even then, the vaccine cost of Rs. 50 crore per year is not a small amount (we are excluding the cost of injecting this vaccine).

If now that the hepatitis-B vaccine cost has been reduced to one fifth, why can't we spend additional Rs. 50 crores for the health of our children?

As we have seen earlier, the most vulnerable and the largest group of children are the newborns of mother with hepatitis-B infection. (Hepatitis-B infection acquired at birth is more likely to cause liver disease later and is more likely to continue to be chronic). Medical textbooks and other authoritative sources including the WHO have recommended that these newborns be given this vaccine within 48 hours of birth.[6] But in India, 77% of births take at home![7] So out of these newborns of hepatitis-B mothers too 77% will not get this vaccine within 48 hours of birth. In the National Immunization programme, the first dose of the Hep-B vaccine would generally be given along with the first dose of the triple vaccine 6 weeks after birth. Thus this **"universal vaccination programme"would not protect the most vulnerable newborns!**

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[6] Jordan R, Law M. An appraisal of the efficacy and cost effectiveness of antenatal screening for hepatitis B. *J Med Screen* 1997;4(3):117-27.

[7] India Human Development Report-OUP, 1999, Table No. 8.8.

How can the topmost experts in India, who have been recommending this Universal Vaccination Programme, have not realised these issues and problems? How can they be so wrong?

This is due to a combination of two factors - Firstly adequate public health expertise amongst those who have been recommending universal vaccination has been lacking. The Indian Academy of Paediatrics - the body of child specialists in India has been very vigorously and consistently advocating this universal hepatitis-B vaccination. Paediatricians are clinicians who specialize in treating individual children. Public Health Policy making is not their area of expertise. Most of them are simply unaware of the various socio-economic facts, costefficacy issues mentioned above. None of them have done the kind of cost efficacy exercise mentioned above, about hep-B vaccine. Most paediatricians have a simplistic understanding that if a "good" vaccine is available for protection from "dangerous" infection, it must be given to all children.

Secondly, there has been a very systematic, powerful, persuasive role of the concerned drug companies. Seminars and other such programmes financially supported by these Pharma companies seem to have biased doctors in favour of giving the hepatitis-B vaccine irrespective of it's advisability from a public health perspective.

This role of the concerned pharma company is exemplified by the publication of the book Hepatitis-B in India. This book is based on the national seminar on 'Hepatitis-B in India', sponsored by the Smithe Kline Beechem company, the multinational which has been manufacturing the Hep-B vaccine. In this book, the article by Thyagarajan et al estimate the prevalence of chronic Hep-B infection in India.[8] It does so by the usual method of aggregating the data from available, published studies in India by different researchers about prevalence of Hep-B infection as revealed by blood- testing. But in this process of averaging, he does an elementary arithmetical mistake!

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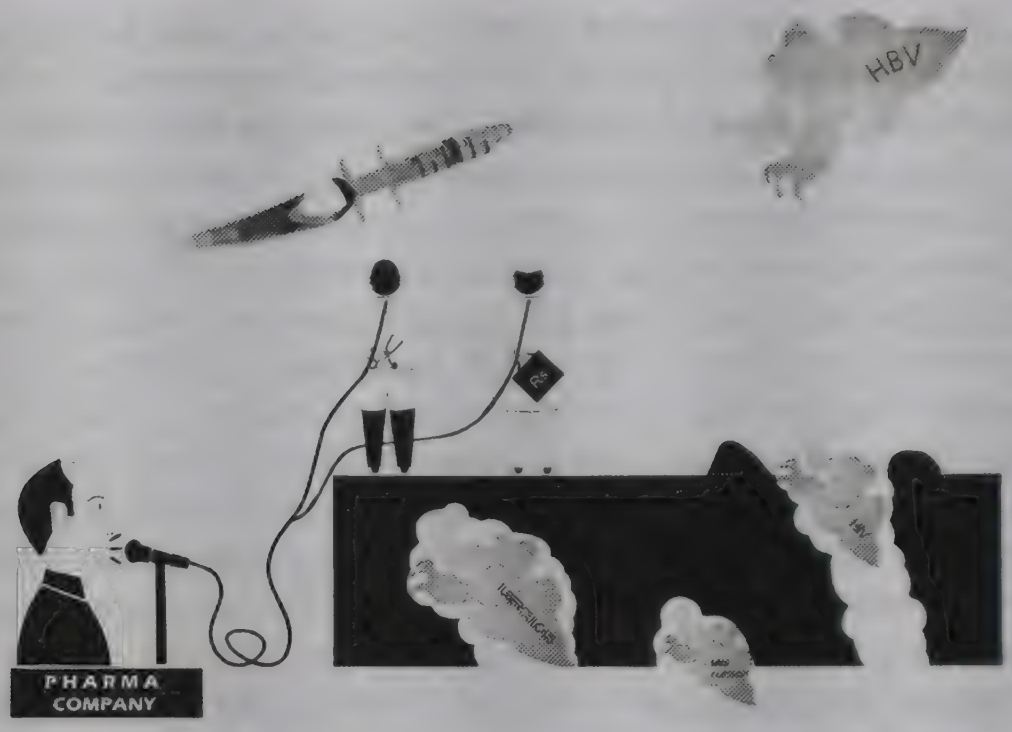
[8] S.P.Thyagarajan, S.Jayaram, B. Mohanvalli. Prevalence of HBV in the General Population of India, in *Hepatitis B in India*, (Ed.) S.K.Sarin, A.K.Singhal, CBS Publishers & distributors, 1996, P.9.



He simply totals up the prevalence rates for Hep-B infection found in these 19 studies and divides this figure by the number of studies to arrive at an average prevalence rate! Even school level arithmetic would tell us that since different studies involved widely different number of persons tested, to arrive at a correct average of these prevalence of Hep-B infection in all these studies, it is necessary to make a total of the persons found to have Hep-B infection and divide it by the total number of persons whose blood was tested. If this is done and if we exclude the four studies on high risk groups like dentists, professional blood donors, which Thyagarajan had included, we arrive at an average 2.64 % of persons tested positive for Hep-B in these nine studies, instead of the mistaken average of 4.7% that Thyagarajan had calculated.

Secondly, Thyagarajan et al gloss over the fact that all those who and found to be positive in the blood test, may not necessarily actually harbour this infection. This is because of the inherent limitation of any such screening test. Hence, a corrective factor has to be applied to this 'positivity rate' to arrive at the actual prevalence rate of Hep-B infection in the population. In case of Hep-B infection in India, this corrective factor called the 'Positive Predictive Value' works out to be 67%. This

means the correct estimation of prevalence of actual Hep-B infection works out to be 2.64 x 67.1% = 1.77%. Thirdly, Thyagarajan et al also gloss over the fact that all these 1.77% of the population do not have chronic infection. Chronic Hep-B infection means persistence of Hep-B infection for 6 months or more. Other studies who have tested blood of Hep-B infected persons again after 6 months found that 80% of them continue to test positive.[9, 10] Extrapolating this finding to this one time test showing 1.77% prevalence to Hep-B infection, we arrive at an average 1.42 % of chronic Hep-B infection. This is by using the same data as used by Thyagarajan et al.

The question that arises is - why nobody pointed out these elementary mistakes in this paper during this national seminar of topmost experts in India! Why was this paper included as it is in this prestigious book? Was it because nobody was interested in critically, scientifically analysing the papers that were presented? Was the whole purpose of the Seminar to create a case of Universal Hep-B Vaccination in India and this included exaggerating the prevalence of chronic Hep-B infection in India ? This suspicion that the Hep-B chronic infection rate is being exaggerated is strengthened by the fact this figure of 4.7% continues to be re-quoted in various meetings and communications, through these mistakes were pointed out by us in a letter published in 'Indian Paediatrics',[11] the journal of the Indian Academy of Paediatrics, also in a letter to the Indian National Association of Study of Liver diseases (INSAL) and in an INSAL meeting in Mumbai in September 2001. Yet this figure of 4.7% continued to be quoted everywhere! There is some problem, somewhere! It is clear that there has been a lobby, which has been pushing this Hep-B universal immunization even if it has no scientific rationale.

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[9] Gupta I., Sehgal R. et al. Vertical Transmission of Hepatitis B in North India. Journal of Hygiene, Epidemiology, Microbiology and Immunology, 36, 1992, No.3, P.265, table 1.

[10] Elavia A.J. & Bankar D.D. Prevalence of hepatitis B surface antigen & its subtypes in high risk group subjects & voluntary blood donors in Bombay, Indian J Med Res [A]93, September 1991. pp 280-285.

[11] Phadke Anant, Kale Ashok. HBV Carrier Rate in India. *Indian Pediatr* 2002; 39: 787.

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Recently a sub committee of the Indian Medical Association, chaired by Prof. S.K Mittal, Jecob Puliyel et al has analysed the data in a scientific way of various studies about Hep-B infection published till 2005 and has arrived at an average Hep-B prevalence rate of 2.1%.[12] If we apply the factor of 80% to this scientific estimation of the prevalence of hepatitis B infection, we arrive at a chronic Hep-B infection rate of1.62% in India. Since this rate is less than 2%, as per the WHO recommendation, India should go for selective Hep-B immunization.

Hep-B vaccination to newborns of Hep-B positive mothers would take care of only the mother to child transmission of Hep-B infection. What about Hep-B infection, which spreads by other means; for example child to child transmission or transmission through sexual relations etc.? Isn't Universal Vaccination of at least all infants be done to prevent these infections, given the fact that we cannot vaccinate all the 100 crore population?

It is true that giving Hep-B vaccination at birth to the newborns of Hep-B positive mothers would take care of only the mother- to child Hep-B transmission, which accounts for one third of the Hep-B transmission. However, as explained earlier this is the most vulnerable group. Vaccinating this group. Which constitutes only 3% of all newborns, would prevent about one third of hep B infections, moreover, those, which are the most damaging of the hep-B infections. This is far more cost-effective than vaccinating every infant.[13] Giving Hep-B vaccine to others is not all cost effective in the Indian context. If we are thinking of reducing the incidence of Hep infection to zero, we should be able to vaccinate each and every newborn for the coming 65 years. (Average life expectancy of life in India is 65 years) so that after 65 years each and every person in India would have received Hep-B vaccine. Assuming

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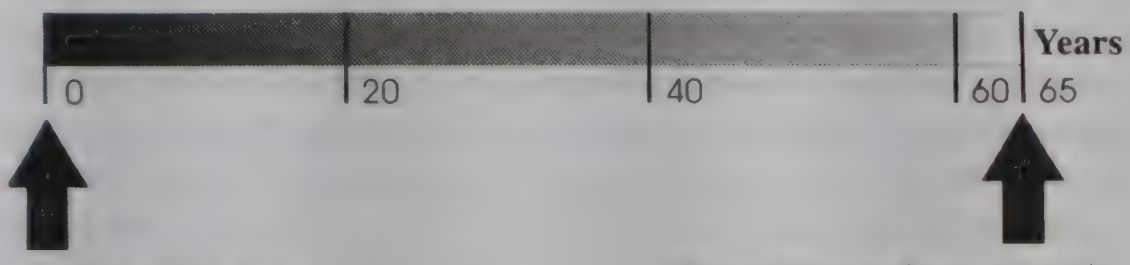
[12] Issues Related to Hepatitis B Vaccination in India: Systematic Review of Literature, May 06.

[13] Kale Ashok, Phadke Anant. Selective Versus Universal Hepatitis-B Vaccination in India. Pediatrics Today, vol.V, no. 4, July 2002, pp. 199- 207.

that Hep-B vaccination is 100% effective (actually it is only 90% effective) after 65 years each and every citizen in India would be protected from Hep-B infection and the incidence of Hep-B infection would be reduce the to zero. We will require 65 years to do this.

(Average Life Span being 65 years)



All new born are vaccinated under Universal Vaccination Program

Every citizen is protected from HBV infection.

- It will take 65 years to protect every citizen from HBV.
- But the Vaccine is only 90% effective.
- Increased risk of multiple sclerosis in subjects who received HBV vaccine.

Secondly, it has now become controversial whether Hep-B vaccination is safe or not. A number of researchers have claimed that Hep B vaccination increases the chances of Multiple Sclerosis - a very serious neurological ailment. A study published in 2004, which was conducted by one of the most renowned epidemiologists and based on one the best data bases in Europe, has very much strengthened this suspicion as it found a three fold relative risk of developing Multiple Sclerosis in the population which has received Hep B vaccination. [14]

[14] Hernan M A, Jick SS, Olek MJ, Jick H. Recombinant Hepatitis B vaccine and risk of multiple sclerosis. Neurology 2004; 63:838:42

Unless this issue of safety of Hep-B vaccine is satisfactorily resolved it would be unwise to launch a programme, which would involve giving this vaccine to millions and millions of children every year for the next 65 years.

Isn't there any way to reduce this vaccine cost?

There is! If this vaccine is given intra dermally - i.e. within the two layers of the skin, only one-fifth the dose is sufficient and yet the resistance acquired to Hep-B infection is equally good. Studies in India have also proved this (A study in infants has also shown this). But the concerned companies are silent about this Intra Dermal route for hepatitis-B vaccine - because this will reduce their sale by 80% ! Even amongst all the doctors who are — for hep-B vaccine for every infant do not talk about this I.D. route, because most of them rely on the drug companies for updating their knowledge.

Our paramedics have been giving intra dermal BCG vaccine for millions of infants every year. Hence giving hep-B vaccine intra dermally to infants would not be problem.

It should be noted that even if we reduce the expense of the vaccine by 80% the cost-efficacy of hep-B vaccine may not match with that of the existing vaccines in the National Immunization Programme.

If the proposal to give hepatitis B vaccine to all infants is dropped, there money thus saved may be used not for Primary Health Care, but may be used for tertiary care or worse, it may be diverted to development of tourism or some such purpose. Instead, would it not be better if it is spent on the hep-B programme even if it is not a high priority issue?

We should refuse to be cowed down to choose between these two wrong decisions. This is because it would mean that whenever we criticize any wrong prioritization, we will be told do not make such a criticism. Other wise the money will be spent on still low priority work. Once we accept hepatitis-B vaccine in the National Immunization Programme without assessing its cost-efficacy, other vaccines are waiting in the

pipeline; would be pushed by the concerned manufacturers; whether these vaccines are cost-effective or not. Some of them in the pipteline are Hepatitis-A, chicken-pox, & H. influenzae vaccines etc.

The only cancer against which a vaccine is available is hepatitis B vaccine, as hepatitis-B causes liver cancer. Why should not protect our people against the deadly liver cancer? Hep-B vaccine also protects against liver cirrhosis caused by hepatitis-B virus. The issue is our priority based on the cost-efficacy; H Influenzae infection is also a very deadly infection causing serious, crippling or killing infection of the brain. We have a very good vaccine against it. Yet we are not including it in the National Immunization Programme because common sense tells us that H. Influenzae the vaccine is costly and there is no disagreement on this. So we are using cost-efficacy as the criterion for taking decision about H. Influenzae vaccine. In case of hepatitis-B, common sense is not enough to decide about its cost-efficacy as there is no agreement whether its cost-effective or not. As mentioned earlier, nobody amongst those who have been advocating the inclusion of hep-B vaccine in the National Programme has estimated the cost-efficacy of hep-B vaccine in India to compare it with that of any of the vaccines currently used in the National Programme. Our detailed estimation shows that the cost per life year saved is respectively Rs.21/- and Rs.353/- for the measles vaccines and hep-B vaccine for infants.[15] In this estimation we have included all the days lost due to all the five chronic illnesses caused by hep-B infection as well as all days lost due to acute illness due to hep-B infection. If we take only deaths caused by hep-B infection around 0.1% of infants are likely to die of hep-B infection later in their life and around 5% of infants with chronic infection are likely to die later due to this chronic infection.[16]

What is your alternative? The "Selective Vaccination" to screen all pregnant women for hepatitis-B infection and to give hep-B vaccine within 48 hours after birth to the newborns who are found to have hepatitis-B infection is also not a very practical alternative.

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15. 16 Comparative Cost-Utility of Hepatitis-B-Vaccination in Indian Infants. Phadke Anant, Kale Ashok, Sept.06 sent for publication.

If at all, we decide to give hep-B vaccine to infants though public funds, this "Selective Vaccination is for more practical and economical then Universal- vaccination of giving the vaccine to every child.

We get many months for testing pregnant woman's blood for hepatitis-B infection. During her Ante Natal Care, any way blood is to be tested for anaemia / diabetes / blood group / HIV. Hence no additional effect would be required for drawing blood for hep-B test. "Card-Elisa" test is available for hepatitis B testing and hence no additional equipment would be required. Its cost today is Rs.30. per test in the retail market. For bulk purchase, the govt. can bring it down to say Rs.15-20. The government is anyway making efforts to increase the proportion of women receiving Ante Natal Care from the current national average of 65%. The main problem is to vaccinated within 48 hours, 3% of newborn whos' mothers have bean found to be hepatitis-B positive, because 77% of the deliveries take place at home.

HBV Vaccine to be effective should be given within 48 hours of birth

Currently, in the Universal Vaccination Program HBV vaccine is given only 6 weeks after birth.

Universal HBV Vaccination Program

is not effecive in preventing infected mother to child transmission

In this form, it is an extreme inefficient use of resources, time and effort.

This problem is not very difficult to solve because we know months in advance which woman's newborn is to be vaccinated within 48 hours after birth.

Out of total new hepatitis-B infections that occur every year, in India, about one-third are from mother to child and by vaccinating just 3% of newborns, we will be able to prevent 33% of these infections! Selective Strategy- is thus not only practicable but is also a highly efficacious strategy. The govt. should first allocate funds for this strategy, as it would protect the most vulnerable and the largest group by vaccinating only 3% of children.

The "Selective Strategy" will not protect two-thirds of the hep-B infections. So what is wrong if all newborns are given hep-B vaccine, so that all newborns are protected?

Vaccinating all newborns with hepatitis-B vaccine starting with the first dose at 6 weeks misses the most vulnerable group and hence is the least efficacious way of giving hep-B vaccine to infants. It is in the interest of the concerned vaccine-manufacturers. Hence it should not be taken up as a substitute for detecting and vaccinating the 3% most susceptible newborns. Looking at various health-care priorities, if budget is available after allocating funds for 'Selective Vaccination Programme', the option of vaccination of all other newborns by giving the first dose at 6 weeks can be considered if we use the Intra Dermal route for hep-B vaccination.

It should be noted that vaccinating all the newborns in the routine immunization programme would protect all newborns from child to child transmission, and not mother-to-child transmission of hepatitis-B infection at least for first 15 years.

If we vaccinate all newborns then all the female babies would be free of hep-B infection when they grow up to become mothers and hence the incidence of mother to child transmission would decrease as they start becoming mothers. This effect would start after say 15 years from today and in 40 years, mother to child transmission in India would stop as all child bearing is completed by 40 years of age.

SECTION II

Concerns Around
Assisted Reproductive Technologies

Now-a-days one hears of new technological options like Artificial Insemination, test-tube baby, selection of the sex of the baby before conception, surrogate motherhood are more easily available.

What exactly are Assisted Reproductive Technologies (ARTs)?

ARTs are a group of reproductive technologies, which assist conception and pregnancy. The category of technologies used for assisting reproduction range from simple or 'low-tech' methods like artificial insemination to 'high-tech' methods such as in-vitro fertilization (IVF) in all its variation. Some are listed below.

1. Artificial insemination by donor or by husband (AID; AIH)
2. In vitro fertilization and embryo transfer (IVF-ET)
3. Gamete intra-fallopian transfer (GIFT)
4. Zygote intra-fallopian transfer (ZIFT)
5. Intra-cytoplasmic sperm injection (ICSI)
6. Surrogacy

A few of these are explained below

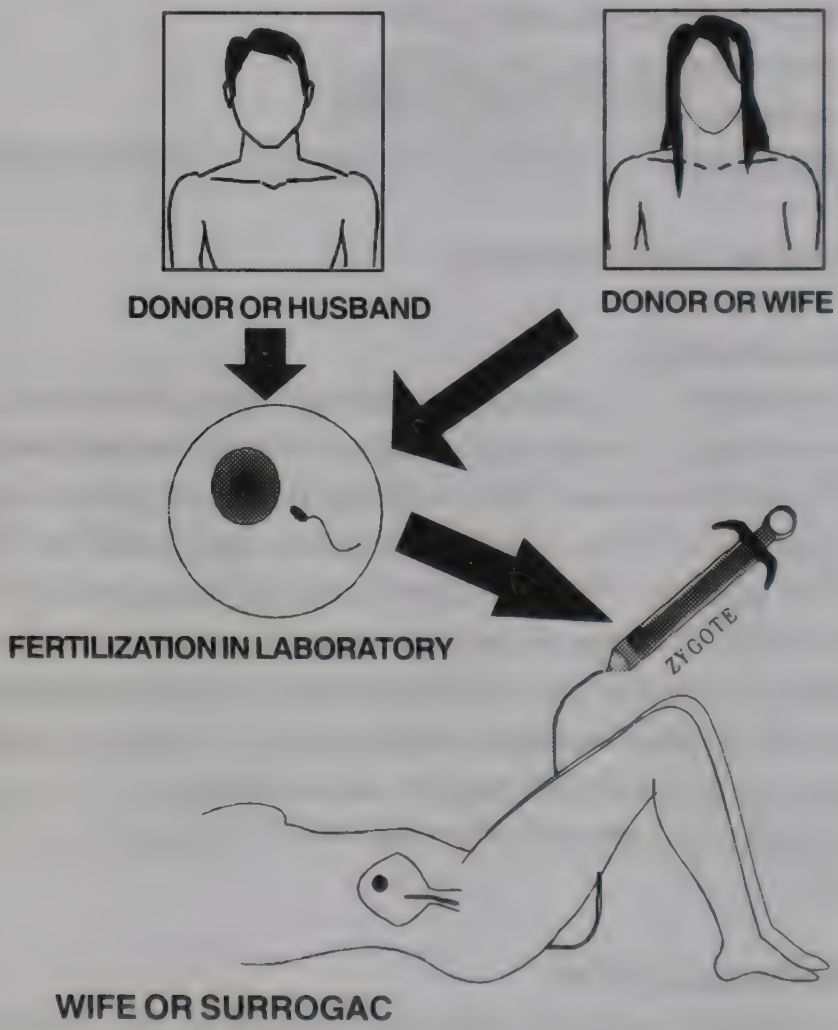
Artificial Insemination

Artificial insemination is a technology through which man's sperm is inseminated in a woman. The sperm is produced through masturbation and not through sexual intercourse. With a syringe the sperm is deposited in a woman's vagina close to the cervix. The sperm used could be that of her husband or partner. This is called artificial insemination by husband's sperm (AIH). The sperm can also come from donors in case the husband/partner is infertile, has a low sperm count, or have a genetic disorder. The latter is called artificial insemination by donor's sperm (AID). During one menstrual cycle, women are inseminated 3-4 times. The procedure is generally repeated over a period of six months i.e. 18-24 inseminations.

In-Vitro Fertilization (IVF)

The IVF procedure consists of several laboratory and medical procedures. The first step is to (hyper) stimulate the ovaries, to produce

(more) eggs. Women have to take hormones (Clomiphene citrate) every day from the second or third day of menstruation. Later in the cycle they have to take hormone injections of HMG (Human Menopausal Gonadotrophin marketed as Pergonal or humegon), which help egg cells to ripen. Blood and urine test along with daily ultrasound is done to determine the time of ovulation. When the largest follicle is about 18mm in diameter, HCG (Human Chorinoic Gonadotrophin, marketed as Pregnyl or Profasi) is injected. The egg cells that are developed are taken out of the follicles. The egg cells then are kept way to incubate and sperm cells are treated. Then the egg and sperm are fertilized in a petridish. Once this is over the egg is replaced in a women uterus.



IN VITRO FERTILIZATION

Surrogacy

The word surrogate means, one that takes the place of another; a substitute or replacement and a surrogate mother is one who lends her uterus to another couple so that they can have a baby. Surrogacy simply put is an arrangement in which a woman agrees to carry a pregnancy, which is genetically unrelated to her, to its full term. However, in case of the surrogate also being a donor of eggs, she is genetically linked to the child, but is carrying the pregnancy for the recipient couple.

Broadly speaking there are two kinds of surrogacy,

- one in which, the surrogate provides the egg and the womb
- the other, where the egg of the couple is used, and transferred to the surrogates uterus by GIFT (gamete intra fallopian transfer) ZIFT (Zygote intra fallopian transfer) or after IVF the embryo is transferred.

In this small piece, by way of example let us deal with only one of these, that is the test tube baby technology (In Vitro Fertilization) . IVF came to be known as testube baby tehnology as, the gametes are fused outside the human body in a petridish or a testube to produce an embryo/ zygote which is later inserted into the uterus.

But does IVF actually treat infertility?

No. What is ironical is the fact that none of these technologies (that are often referred to as infertility treatment) treat infertility per se (the cause of it) but only assist in producing babies.

Since when is IVF available in India?

World's first documented IVF baby Louise Brown was born in July 1978. In India in the same year in October, Dr. Subhas Mukherjee in Kolkata announced the birth of IVF baby Durga. The case was presented but not published in a scientific journal for peer review since the experimentation was not properly documented. Harsha, the first documented IVF child was born in 1986 in the government research programme at the National Institute for Research in Reproduction (NIRR), Mumbai.

What is the philosophy behind introducing IVF?

Initially IVF was viewed as providing a solution mainly for women who could not conceive due to blocked tubes. But today the range has widened to 'aid' women without uteruses, or no eggs of their own, menopausal women, infertile and sub-fertile men, all of whom can now have the potential to have their own 'biological' child. Increasingly these technologies are claiming to not only provide help in having children (assisting birth) but also in producing 'better' quality of children.[1]

It is interesting to note that the history of assisted reproductive research in India is in actually a consequence of the population control agenda of the government. As the ICMR Bulletin (Vol.14, No.10. October 1984) says --due to high infant and child mortality, several women who have undergone tubal sterilisation do seek tubal recanalisation - IVF/ET requires comparatively less intervention than tubal recanalisation. If a couple is convinced that pregnancy could be achieved with certainty by the IVF/ET technique, in the event of their losing the existing children, they might readily accept tubal sterilisation as a method of family planning. Thus in vitro fertilization could be of great relevance to our national family welfare programme.

It obvious that ART can be manipulated as an instrument in the hands of the population controllers to further their larger objective and provide justification for rampant sterilisations. It also reflects programmatic and scientific linkages between contraceptive and conceptive technologies. However, NIRR discontinued the research later and 'infertility-treatment' was not introduced in the public sector.

Despite government's initial investment on research in infertility, the infertility business has shifted to private medical sector today. It is a growing industry that operates within a profit paradigm and infertility is projected as the new/latest "disease" and therefore the need to treat an otherwise healthy body. Not surprisingly therefore, IVF is incorrectly

[1] Gupta, Jyotsna Agnihotri (2000) New Reproductive Technologies, Women's Health and Autonomy- Freedom or Dependency? pp 336

publicized as an established and successful therapy rather than a still experimental and largely 'research and development oriented business'. Media has also played a significant role in popularizing and establishing IVF by reporting on 'miracle babies' and medical breakthrough rather than presenting a balanced picture.

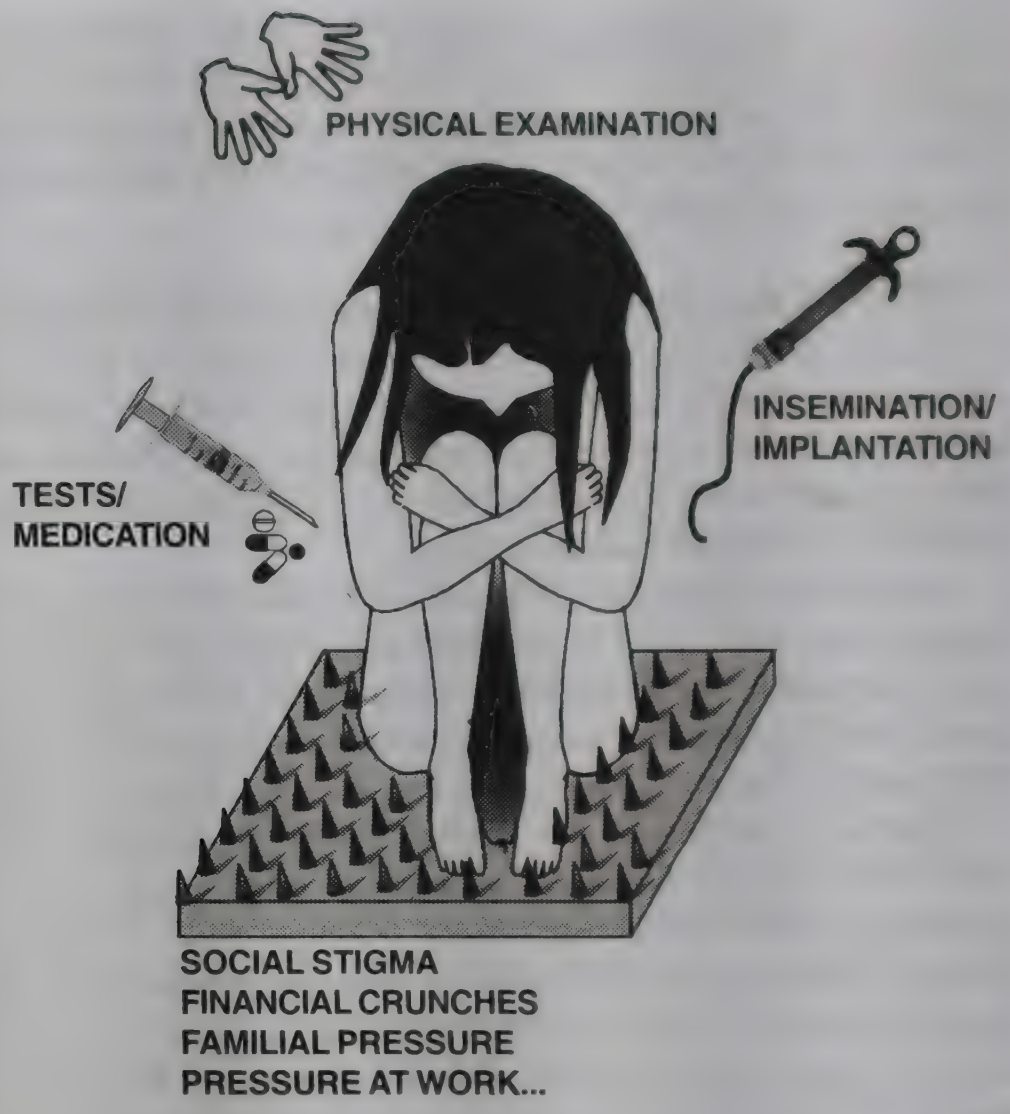
Why has there been such a rapid growth in this industry?

Certain factors are responsible for the phenomenal growth of the IVF industry. On the one hand, with infertility treatment stabilising in the major (western) markets, India has emerged as an attractive market. This is especially so as the society here lays a high premium on marriage, childbearing and continuance of lineage..

Seizing the opportunity IVF and ART centres have opened up in virtually every state, both in rural and urban areas. The quality of the service of course varies but most small towns and villages too have clinics providing 'infertility treatment',. Government policies that support ARTs have also played an important role in expanding the market.

The National Council for Applied Economic Research report on GATS and Medical Tourism argued that India would be a major beneficiary on medical tourism once WTO Rules and GATS come into full force. This is because it has all the necessary resources, in terms of qualified doctors, a healthy private health sector, a pool of trained nurses and other personnel to effectively provide treatment to the patients from abroad. This was followed by several reports commissioned by the private healthcare industry to convince the government to facilitate opening up the medical tourism market. Thus, private hospitals are able to get financial incentives like low import duty on medical equipments, raise capital at low interest rates, special 'medical visa' to smoothen difficulties faced by patients, joint ventures with insurance companies etc.[2]

[2] Mulay, Shree (2006) 'New Climate for marketing of New Reproductive Technologies and Implications for Regulatory Process' (unpublished draft article)



In this specialized industry every provider promises of providing something special to his or her clients, a customized care. Parental-choice now encompasses more than having children, it enhances the choice through sex-selection and /or genetic screening of having the 'perfect designer baby', which help in promoting new eugenic consciousness. The industry has not only usurped and manipulated the concept choice that was a mainstay of the women's movements to attract a range of customers but has also commercialized body parts by creating or providing a 'choice' to eggs, rent wombs and the like.

The ART market is cashing in on women's supposed 'desire' for being a mother and the couples 'need' of having a biological child of

their own. There is little concern on the effect of these technologies in the lives of women though it is they who undergo invasive medical probing, drug programmes, and surgical interventions in the medical research determined in its effort to give a successful assisted child birth.

How successful are these techniques and what do they cost?

IVF has become a growing industry that operates within a profit paradigm where infertility is projected as the new/latest 'disease'. IVF is incorrectly publicized as an established and successful therapy rather than a still experimental and largely 'research and development oriented business'. There is huge publicity of the rare successes but silence around the large number of failures, miscarriages and even deaths of young women[3]. Though internationally the success rate of IVF (live birth per cycle/take home baby) is quoted to be 25% until the age of 34 years, after which there is steep decline[4], the absence of a central registry monitoring IVF clinics has led to the widening of the definition of successful pregnancy to include implantation rate (that may not lead to a live birth) and chemical pregnancy (change in hormone level that may not actually lead to conception) in order to heighten the success rate.

In India success rates in this market has been quoted to be as high as 40% in the various promotional sites of ARTs. But the reality is that it varies widely in relation to the age of the woman who undergoes treatment. Also what is usually quoted, as success rates are success rates at implantation whereas the actual success rate needs to be calculated with respect to the take home baby rate. Analysis of 2,500 couples,

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[3] Franni, Vincent (1996) 'An Examination of the assumptions about motherhood and feminine agency which are embodied in debates about the new reproductive technologies'

[4] Society for Assisted Reproductive Technology and The American Society for Reproductive Medicine, Assisted Reproductive Technology in the United States and Canada: 1995 results generated from the ASRM Registry, cited in Mahmoud, F Fathalla 'Current challenges in Assisted Reproduction' in Current Practices and Controversies in Assisted Reproduction, Report of a Meeting on Medical, Ethical and Social Aspects of Assisted Reproduction WHO 17-21 Sept 2001

aged 25-29 yr undergoing 4,777 IVF-ET cycles showed a cumulative pregnancy rate of approximately 60% over up to six cycles. However, there was an expected drop in pregnancy rate form 24.4% in women between 30 and 34 yr to 14.7% in women above 40 yrs of age.[5]

SUCCESS RATE OF A. R. T.

AGE GROUP (YEARS)	CUMULATIVE PREGNANCY	BABY TAKE HOME RATE
25-29	60%	25% of the cumulative
30-34	24.4%	pregnancies
40 and above	14.7%	

The success rate per cycle is estimated to be around 20-30% and costs range from 50000 to 75000 and can even go a upto 1 lac per cycle.

What are the medical implications of these technologies? Can there be health hazards for the woman involved?

The invasive medical procedures and drug regimes that women are required to go through during the 'treatment' affect them physically. Systematic analysis of Studies reveal that many of the physical side effects of ART are direct by-products of the drugs like Pergonal and Clomiphine that are used in connection with stimulating the ovaries to produce eggs:· Ovarian hyperstimulation (OHSS) - Severe form of OHSS may lead to renal impairment, liver dysfunction, thromboembolic phenomena, shock, and even death.

- In 25 per cent of ART there occurs multiple gestation pregnancies (incidence of only 2% in the general population)

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[5] 'Need And Feasibility Of Providing Assisted Technologies For Infertility Management In Resource-Poor Settings' in ICMR Bulletin Vol 30.No 6-7, June-July 2000

These increase the danger of miscarriages, cesarean sections, early labor, and placental dysfunction·Increased risk of pregnancy loss, premature delivery, infant abnormalities, pregnancy induced hypertension, hemorrhage. Ovarian twisting - less than 1 per cent of the time the stimulated ovary can twist on itself, cutting off its own blood supply· An increased risk of ovarian cancer- controversial data exists that associate ovarian stimulation drugs to the risk of future ovarian cancer.[6]

The risks relating to the procedures involved in ARTs are

1. Laparoscopy and ultrasound-guide oocyte retrieval pose risks of:

- postoperative infections
- punctures of an internal organ
- hemorrhages
- ovarian trauma, and
- intra-pelvic adhesions

2. Possible risks of Implantation of embryos or gametes into women's bodies are:

- Perforation of organs
- Ectopic pregnancies- 5-7% of all IVF pregnancies implant outside the uterus. 1% in the general population

3. Morbid risks of foetal reduction include:

- uterine bleeding
- developing infection,
- premature labour and
- loss of all fetuses

Not only is there an absence of standard diagnostic and treatment protocol, the costs of treatment also vary considerably, depending upon

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[6] [Reference:Medical Research Institute, Society of Assisted Reproductive Technology, The American Fertility Society, In Vitro Fertilization/ Embryo Transfer in the United States: 1988 Results from the National IVF-ET Registry, Fertility and Sterility(1990)]

the spending capacity of the couple. The doctors are of several opinions when asked about the cost and efficacy of the IVF treatment -

"If I don't treat them they will go somewhere else & You can't make people spend if they don't want to."

"The drugs may have risks, but they can improve the couple's quality of life"

"If they want the treatment, who are we to decide?

"Helping a woman have a baby is a doctor's greatest accomplishment"

Notably, there is poor documentation of tests and treatments, and each time when the couples change the doctor tests are repeated and treatment starts afresh. Extensive and unmonitored use of drugs which increases the risk of multiple births, and unapproved drugs with known risks promoted by drug companies (letrozole), sex selection and inadequate staff and facilities form a range of problems with IVF clinics. Moreover, the chances are that IVF clinics will be the suppliers of research materials and have the potential of exploiting poor women for ova, embryo and other reproductive materials.

Mental Health is an important aspect that needs to be taken into account also is the experience of undergoing infertility "treatment". The effects on women's mental and emotional health is immense. Couples undergoing treatment face the cycle of hope that the woman will conceive this time to be followed by feelings of helplessness, inadequecy and despair when each attempt fails. Thus, there is a continuous mental stress that they have to undergo especially the women, without any clear solution. The intensity of the drug procedure, the frequent visits to the clinic, the ultrasound scanning, the blood tests, the dangers and stresses of the operations, the humiliation of infertility and the agony of waiting for results at different stages of the treatment[7] add to the mental pressure.

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[7] Women's Health Council: Position Paper on Assisted Human Reproduction: The Health and Social Implications for Women http://www.whc.ie/publications/position_reprod.html pp 7

Specifically, some aspects of treatment may also cause gender-specific emotional and psychological distress. In fact, many men feel humiliated at producing a sperm sample through masturbation, and some women feel that repeated internal exams are similar to sexual violence.

Risks to the child

- Few studies have shown that the incidences of pre-term births and low birth weight are high in case of ART[8]. There is 30% chance of multiple births in cases where more than one embryo is transferred. There is also significant increase in infant mortality and morbidity.
- Perinatal mortality rates are fourfold for twins and six-fold higher for triplets, while cerebral palsy rates are 1-1.5% in twin and 7-8% in triplet pregnancies[9]. Another study says that children born from a multiple gestation are at increased risk of cerebral palsy, learning disability, and learning and neurobehavioural deficits[10]. There is also a clear increase in sex chromosome abnormalities in the ICSI baby. The rate of sex chromosome abnormalities is 1% compared to 0.2% in the general population[11], i.e. 5 times greater!

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[8] Wang Y.A et al (2005) 'Preterm birth and low birth weight after assisted reproductive technology related pregnancy in Australia between 1996-2000' in Fertility Sterility June 83 (6) pp 1650-8 cited in Sama-Resource Group for Women and Health: Assisted Reproductive Technologies: Medical and Social Implications for Women (unpublished document), 2006

[9] Wimalasundera R.C. et al (2003) 'Reducing the incidence of twins and triplets' in Best Practice and Research: Clinical Obstetrics and Gynaecology April 17 (2) pp 309-29 cited in Sama-Resource Group for Women and Health: Assisted Reproductive Technologies: Medical and Social Implications for Women (unpublished document) 2006

[10] Rand L, Eddleman KA & Stone J (2005) 'Long term outcomes in multiple gestations' in Clinics in Perinatology June 32 (2):vii pp 495-513 cited in Sama-Resource Group for Women and Health: Assisted Reproductive Technologies: Medical and Social Implications for Women (unpublished document) 2006

[11] 'Funding in-vitro fertilization treatment for persistent sub-fertility: the pain and the politics' in Fertility Sterility, 2001 Sept 76 (3) cited in Sama-Resource Group for Women and Health: Assisted Reproductive Technologies: Medical and Social Implications for Women (unpublished document) 2006

- The drugs used in the "treatment" can also affect the foetus and the infant. For example, between May 2001 and April 2004, 7 children between the ages of 5 and 21 months conceived by ART were presented with breast development and /or pubic hair to the paediatricians in the New York University School of Medicine. The clinical presentation in these infants raises awareness that an altered intrauterine hormonal milieu may impact the foetal and infant stages of children conceived by ART[12].
- Reports of sporadic cases of imprinting disorder, Angelman syndrome (a severe disability syndrome with abnormal behaviour, movements and mental retardation) have also been linked with ARTs[13]. The frequency of BWS (Beckwith-Wiedemann Syndrome, an abnormality where the babies develop abnormally large organs and have predisposition towards tumour) is higher in babies conceived through ARTs. As compared to 1 in 15000 in general population, two reports of children born through ARTs showed it to be 1 in 73 and 1 in 91 children[14].

Off late surrogacy has been widely reported what exactly are the debates involved?

Surrogate motherhood involves using a woman's womb to grow somebody else's baby and hence raises some very pertinent questions around the very method. While there have been debates over surrogacy, status of embryos, sale of embryos etc, women who plays the central role in the entire process have been largely ignored. Commercial surrogacy, is a reality in states such as Gujarat and the doctors have no reservations about commercial surrogacy as the woman is seen as using her resources - in this case, her womb - to earn money for an honourable cause.

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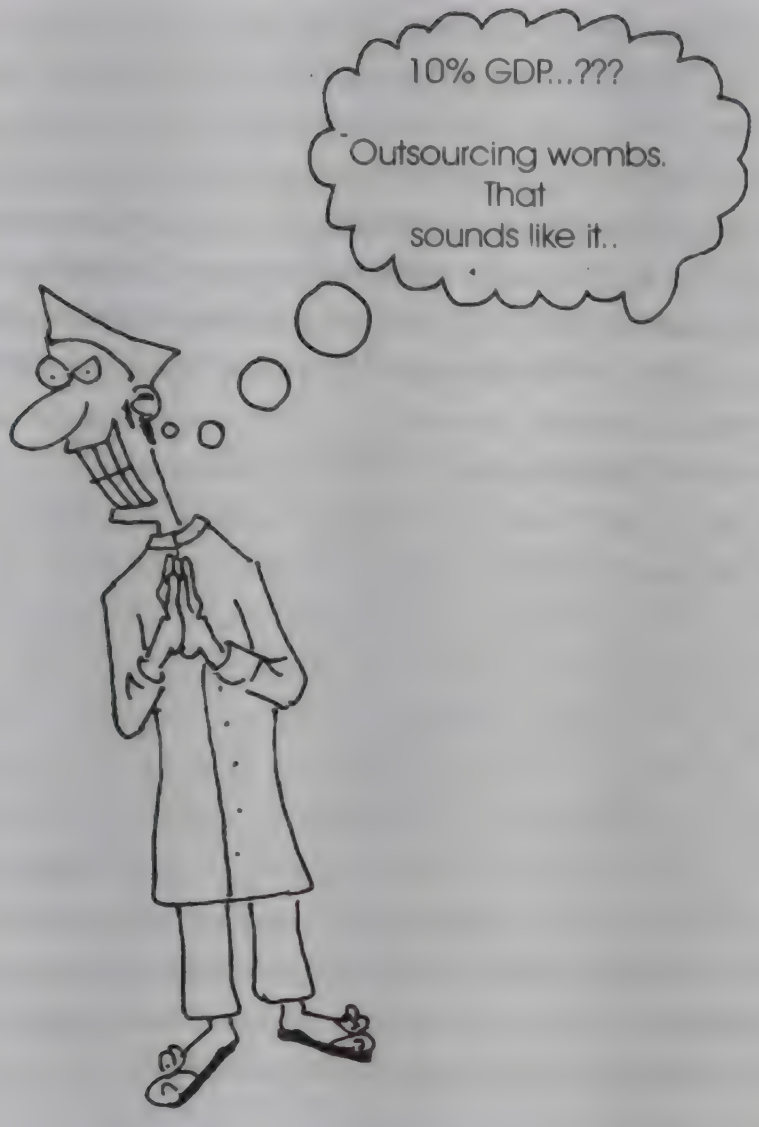
[12] 'Hormonal effects in infants conceived by assisted reproductive technology' in Paediatrics 2005 July 116 (1) pp 190-194

[13] Gosden R et al 'Rare congenital disorders, imprinted genes and assisted reproductive technology' Jones Institute of Reproductive Medicine cited in Sama-Resource Group for Women and Health: Assisted Reproductive Technologies: Medical and Social Implications for Women (unpublished document) 2006

[14] Maher, E.R, Brueton, L.A. et al (2003) 'Beckwith-Wiedemann Syndrome and assisted reproductive technology (ART)' in Journal of Medical Genetics Vol 40 pp 62-64 cited in Sama-Resource Group for Women and Health: Assisted Reproductive Technologies: Medical and Social Implications for Women (unpublished document) 2006



The Week July 9 2006 had a cover story on surrogacy wombs for hire - where till date, 15 women in Anand, a city with only 2.5 lakh population, have opted for surrogacy with support of the husband for money to keep the families running. With an IVF industry worth thousands of crores of rupees, surrogacy can earn a woman somewhere between Rs 1-3 lakh. It is being projected as India's next big outsourcing business. Women are doing it for strangers, renting out of wombs but prefer to hide their children. ICMR in this regard issued the statement that 'no woman can surrogate more than three times'. Does it mean it is

ok to surrogate for 3 children? What about the health implications of undergoing numerous pregnancies since the surrogate should have had atleast one child? The article suggested that surrogacy has all the trappings of an industry, except legislation and the only **law applicable at present is the Indian Contract Act,** as the surrogate mother has to sign off her rights on the child at the time of agreeing to surrogate[15]. Surrogacy also involves unresolved questions around the rights of the surrogate, rights of the intended parents, rights of the child, veracity of informed consent, threat to family unit because of third party involvement in procreation etc. The opponents of surrogacy also argue that this amounts to slavery and baby selling, thereby undermining the view of motherhood Moreover, women who provide reproductive tissues or services tend to be from lower socio-economic groups, whereas recipients tend to be more socially and economically advantaged. Reducing treatment costs by "sharing" ova or embryos is a form of sale: the donor's treatment is paid for by the recipient in exchange for acquisition of gametes or embryos. "Sharing" programs may also undermine informed consent, as the strong desire to have children (and thus to attempt IVF) may overshadow the implications of donation for both the donor and recipient. In cases of egg sharing or egg donation, the regret might be severe if the donor later experiences infertility or, in sharing programs, a failure of IVF for one of the women.

Some people use this new technology for as an opportunity to make money. But keeping aside the misuse and the medical implications for the women involved, what are the other concerns?

As discussed above the technology and treatment with specific reference to infertility cannot be viewed as only as medical or scientific concerns there are a range of issues that create the social context within which they operate and also these technologies will have a range effects on this context.

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15 'Wombs for Hire' in The Week July 9 2006

Health seeking for infertility is rooted in the cultural/religious norms of childlessness and the desire for a male child. This desire to have a child is significantly influenced by societal assumptions about women's mothering role and, to a certain extent, about men's virility as a mark of masculinity. The gender-specific perceptions that "pregnancy makes a woman complete" or "real men get women pregnant", creates tremendous pressures and feelings of inadequacy, failure and abnormality among infertile couples. Gender issues are thus central to the ethics of assisted reproduction.

Indeed, ARTs have made it harder for some women to end their pursuit of maternity. Women take reproductive decisions as members of a society that believes a woman's primary function to be motherhood. The assumption throughout is that 'infertile' women are somehow not fulfilling their 'natural' goal of motherhood. The choice therefore is limited within this framework and the socialized desire to mother is so deep rooted that women rarely can consider any alternatives. Moreover, the choice is influenced by other social factors like class, caste, gender, sexual orientation, age, religion, marital status etc. Despite changing patterns of women's work and more economic participation in work outside home, there is still an assumption that women's participation in marriage and subsequent motherhood is the ultimate goal. Within such a context, technology has allowed woman, not just to produce a baby, but also ensure that it is a physically perfect one, which includes one of the 'right' sex. This becomes an end, which excuses the invasive methods of infertility 'treatment'. The increased pressure for infertility treatment comes in part from the general awareness that infertility is no longer necessarily untreatable. The social stigma of infertility therefore makes it imperative to demand for these technologies. Thus, examining assumptions about motherhood in the light of the issues of infertility itself shows just how little choice women actually have.

The strongly held patriarchal perception in the Indian context that believes son to be the 'propagator' of the 'vansh' (ancestral line) also takes away the choices of adoption. Not only does the woman not have any choice in not having a child but also no choice of how to be a mother. In some senses motherhood per se play a secondary status from being

the mother of a 'biological' son. A point where the woman's own aspirations stop and the quest for a male child begins. The doctors, as products of the same society and also because of economic interest never present the possibility of adoption as a viable alternative when infertile couples come to seek 'treatment'. Moreover, the ideas of ownership, that a woman's womb is the property of her husband and hence the product i.e. the child belong to the husband, diminishes women's agency to the extent that the woman may often say "it has to be his (husband's) sperm, and I don't care whose egg it is". In such a situation woman's right to her bodily integrity stands to be completely violated, since the woman who is required to undergo the treatment may not be voluntarily opting for it.

Are there any ethical problems in producing 'test-tube babies'?

There are various ethical concerns that come into play when we discuss ARTs. A lot of these concerns have been discussed above but broadly speaking ethical concerns have been raised for two reasons

1) Context in which such technologies are used
2) Inherent nature of specific techniques used

Informed choice & informed consent are both areas in which ethical aspects are to be followed and monitored closely.

But are they being looked into at all?

Research on the efficacy, long-term safety and psychosocial implications of most ARTs remains incomplete, but new techniques are rapidly introduced into clinical use without 'patients' (and many clinicians) knowledge that they are still experimental. Ethical considerations demand that explicit clarification must be made that these procedures are experimental, innovative, common but not yet truly validated, with special attention to possible risks. Moreover, research on embryos must be understood as a women's health matter, since embryos cannot be acquired without first retrieving ova from women. When ova or embryos are sought for use in research, the fundamental ethical consideration must therefore be the well being of the donor. The patients

or donors are quite often exploited in the interests of research or financial gain. The demand for ova and embryos for research is expected to increase as a result of recent advances in stem cell research for possible tissue transplantation.

Certain questions need to be asked in relation to informed consent

- ***Does social/cultural/religious/market context allow free and voluntary choice?***
- ***Is spousal consent essential? For what purposes? Does it include only husband's consent in woman's choice or also in man's decision to donate sperm?***
- ***Is there sufficient information available on the ARTs to enable person(s) to make free and informed choice?***

Ethical concerns also veer around the possibilities of new familial relationships. IVF allows a woman to gestate a fetus genetically unrelated to her, either as the recipient of an ovum or embryo donation or as a contracted surrogate mother. Both genetic and gestational mothers are biological mothers, but neither is consistently identified as the legal mother. In special circumstances as many as 5 adults may play parenting roles in ARTs: the genetic mother and father (ovum and sperm providers), the gestational mother and the intended social parents. Each party has his or her own interests and vulnerabilities. Other family variations- such as women who bear their own genetic grandchildren, postmenopausal pregnancies and reproduction by members of same-sex couples- challenge social, legal and historical norms.

Donor Anonymity: ethicists also argue that though donor anonymity protects the privacy of donors and recipients, it undermines the interests of offspring regarding their genetic medical history and ancestral heritage. Techniques like Preimplantation Genetic Diagnosis (PGD) raises question around its use to eliminate undesirables. Though such genetic diagnosis are to focus on severe diseases rather than traits such as sex or appearance, it opens up new areas of discrimination and ambiguities around the definitions of "disease".

How then are these clinics and procedures regulated and monitored?

Although most Western countries have adopted legislation to regulate ARTs, the Indian Government has yet to do so. Lack of regulation is another concern since the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India appeared in 2005 after the draft guidelines were formulated as early as in 2000. Not only do the ICMR (Indian Council for Medical Research) guidelines endeavour to glorify the technology at various points but also construct infertility as a disease and the infertile as patients. This actually makes medical intervention not only a necessity, but also the only way to deal with infertility. It also claims IVF to have the highest yield per attempt, coming close to conceiving naturally. When the real take home baby rate with IVF is only between 15-25 percent, such rhetoric will not only mislead the infertile people, but also lead to further invasion of women's bodies by the medical establishment.

Though there is a mention of the responsibilities and composition of the National Advisory Committee and the State Appropriate Authority, the scope of these committees and its modus operandi to implement its powers are not brought up comprehensively. Moreover, there are no details of the scope of the National Accreditation Committee and its responsibilities, whether it has any executive powers and what could be the qualifications of various members in this Committee etc[16].

The guidelines also holds an ambivalent stand regarding the maximum age of the woman going for ART though it maintains that menopausal women can undergo these techniques. Moreover, the health implications of ART on menopausal women is not spelt out anywhere in the document. The ICMR guidelines prohibit the sale of human embryos to any party outside the country. However, within the country they are available to bonafide researchers only as a gift having no commercial interest.

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[16] Sama-Resource Group for Women and Health (2006) Assisted Reproductive Technologies: Medical and Social Implications for Women (unpublished document)

The question that immediately arises is who will identify their authentication? How will it be ensured that there is no commercial transaction taking place when there is such growing interest in embryonic stem cells [17]*?*

India has no appropriate stand on the issue of embryonic stem cell research. In such a situation providers can indiscriminately sell embryos to other countries, since there is no regulation. Most importantly, the ICMR guidelines do not have any legal binding, and in a situation of strong lobbying by the private practioners any new legal instrument is at risk to strive to safeguard the interest of the IVF providers, and not that of women, society at large, and the basic principles of ethical practice.

Conclusion

This is an era that is seemingly accepted "industrialization of reproduction", the technologies and arrangements are a political issue. Not only do they reflect the lack of power women have over their bodies but also of the degree to which female body is accessible in the reproductive realm. The image of the woman as a reproductive object is reinforced through these technologies.

The distress caused by infertility clearly deserves a comprehensive and rational response. The difficulty lies in ensuring access to medically necessary and appropriate treatment while avoiding inappropriate overuse at both micro (individual patient) and macro (health policy) levels. Lack of restriction for ARTs promotes suboptimal treatment for less wealthy women, and the use of incompletely tested technology. Providing the safest and best available treatment for a patient's needs is essential to ethical health care service.

At a macro level, accountability and justice in the distribution of resources create new tensions and frustrations in a publicly funded health care system. Decisions regarding whether to cover specific health care interventions must be justified by continual evidence-based assessment

[17] Ibid

of the intervention's safety and effectiveness, the full costs of the intervention to the health care system (e.g., total costs per successful outcome and the costs of complications) and the availability and comparative results of other options. The social effects of increased usage, such as reinforcement of pro-natalist attitudes in the case of assisted reproduction, must also be considered.

Today, the fertility business exercises greater control over women's bodies, and promotes the "genetic imperative" where the desire for a child may be stronger than the risks involved. Thus, in many ways IVF has led to overmedicalization and reinforcement of patriarchal social values. An individualized "quick-fix" solution of a social problem. There is dearth in addressing macro-epidemiological, underlying causes of infertility, such as environmental pollution, workplace routine, toxicity, untreated or undiagnosed PID (Pelvic Inflammatory Disease) and so forth. Medical research, education and practice should emphasize the protection and restoration of reproductive health, where possible, instead of propagating IVF methods that merely circumvent infertility.

In order to gain a complete picture, it is important to understand therefore, the political context of the development and spread of ARTs, which have consequences for both men and women. The multinational corporations set the agenda of our country today by capitalizing on the social pressures of biological motherhood. This makes women doubly disadvantaged and objects of other's choices. The whole gamut of possibilities of voluntary childlessness, of adoption, of changed social structures and social relations never finds a place in this forceful market driven ideology of assisted reproduction.

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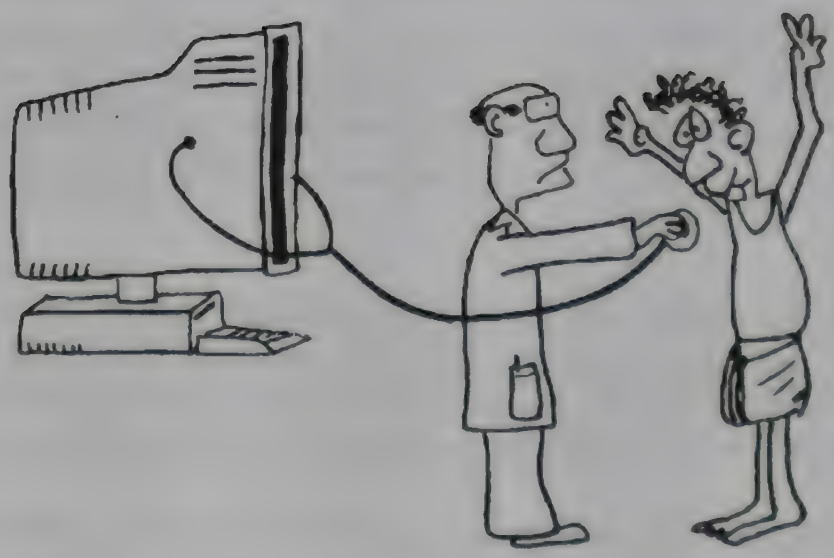
We acknowledge the inputs from Dr Anant Phadke.

SECTION III

Bio-technologies and Information Technologies

Their implications for public health



1. Genomics and Health: Ethical and Social Implications

The current revolution in genomics, culminating in the sequencing of the human genome, has tremendous potential to improve health globally. The human genome undoubtedly offers unprecedented opportunities to all countries for understanding mechanisms of disease and developing new drugs and vaccines. All the drugs in the world act on only 479 known molecular targets. If only 10% of the genome represents targets for new drugs the possibility exists for developing at least 3000 new molecular entities to combat disease. Through new technologies 50 000 new drugs can be produced and screened by a laboratory in a weekmore than a major pharmaceutical company could test in a year. Already new vaccines are under development that has been derived directly from the DNA sequence of the pathogen. The possibilities offered by the identification of genes responsible for various diseases are opening up the possibilities of early detection of these disorders by genetic screening and their management using gene therapy and genetic manipulation. New genomic diagnostic technologies are on the anvil that can completely revolutionize the diagnostic armamentarium of the medical profession.

Ethical and Social Problems

While all these developments give us a lot of optimism in tackling the health problems of the people more efficiently and scientifically and also to solve many of the still unresolved health problems like genetic disorders and cancers, genomics brings with it complex new ethical, legal, social, and economic implications as well as concerns about risks and hazards. Issues of confidentiality, stigmatisation, and misuse of genetic information are high on the list of concerns. Intellectual property rights associated with DNA sequences and the potential exploitation of populations in developing countries by creating genetic databases, often at the behest of companies based in the developed world, are other areas of major concern.

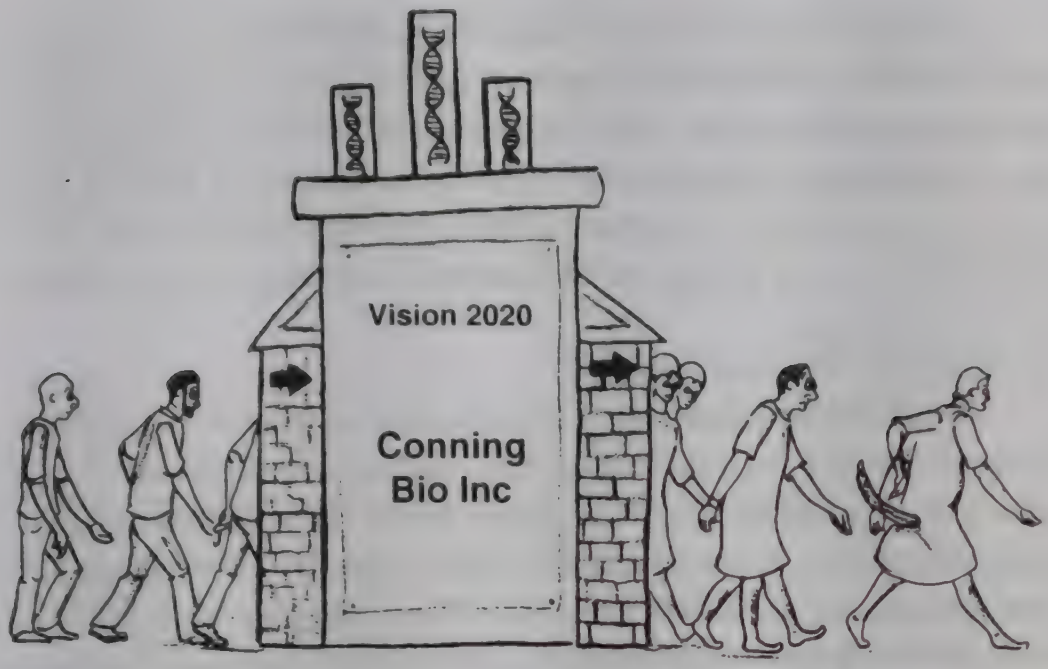
Of particular interest is how these advances will affect the health of people living in the developing countries. The reality that much of the advances in genomics were made, and in part are owned, by the developed world has given rise to the concern that a genomics divide will be created that will further widen the equity gap in health between rich and poor nations. In fact, genomics and related technologies should be used to narrow the existing unethical inequities in global health.

ELSI Project

While the information gleaned from the human genome could revolutionize medicine, many believe the new era of genetics needs a new type of ethics. Some fear that concerns about the applications of this new knowledge are being ignored. Dr. James Watson the first director of the Human Genome Project of the National Institute of Health USA was aware of the possible social implications of the deciphering of the human genome sequence. He took the initiative to establish the ESLI (Ethical, Social and Legal Implication) project as part of the Human Genome Project to study the various social impacts of human genome sequencing. The Welcome Trust the charity organization who has invested 80 million pounds in the human genome admitted that it fears that the work could lead to individuals being disadvantaged because of their genetic make up and said that this concerned needs to be addressed by legislation. The Campaign against Human Genetic Engineering a group of researchers scientists and doctors concerned about possible misuse of genetics believes that the public had been given exaggerated gains from the project.

Fears of Genomics

The new genetic science raises more troubling issues than any other technology revolution in history. In reprogramming the genetic codes of life, do we risk a fatal interruption of millions of years of evolutionary development? Might not the artificial creation of life spell the end of the natural world? Do we face becoming aliens in a world populated by



cloned, chimerical, and transgenic creatures? Will the creation, mass production, and wholesale release of thousands of genetically engineered life forms into the environment cause irreversible damage to the biosphere, making genetic pollution an even greater threat to the planet than nuclear and petrochemical pollution? What will be the consequences for the global economy and society of reducing the world's gene pool to patented intellectual property controlled exclusively by a handful of multinational corporations? How will the patenting of life affect our deepest convictions about the sacred nature and intrinsic value of life? What will it mean to be a human being in a world where babies are genetically designed and customized in the womb and where people are identified, stereotyped and discriminated against on the basis of their genotype? What are the risks we take in attempting to design more perfect human beings?

The human/animal hybrids could be widely used as experimental subjects in medical research and as organ 'donors' for xenotransplantation. The artificial creation and propagation of cloned, chimerical, and transgenic animals could mean the end of the wild and the substitution of a bio-industrial world.

Genetic changes could be made in human fetuses in the womb to correct deadly diseases and disorders and to enhance mood, behaviour, intelligence and physical traits. Parents might be able to design some of the characteristics of their own children, fundamentally altering the very notion of parenthood. It is feared that customised babies could pave the way for the rise of a eugenic civilization in the twenty-first century.

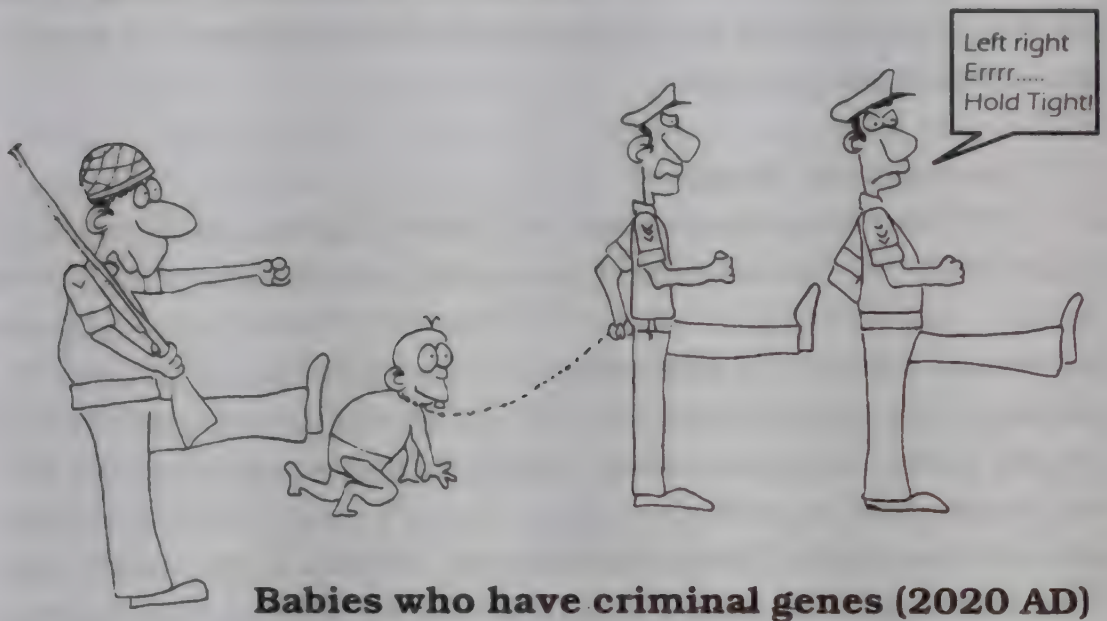
Genetic Discrimination

The most immediate use of the information provided by the Human Genome Project is in genetic testing, and we are promised that these tests will tell us much about our future health. If privacy is not ensured, and institutions are not restrained from using the information in their own interest, the result will be genetic discrimination. Such information is not only of personal interest to us: employers, insurers and many other institutions may use this information for their own interests.

This is not a futuristic possibility: surveys in the USA show that nearly 50% of people with genetic disorders in their families had been discriminated against by insurers. In the UK one-third of the people surveyed had problems with insurance, and 13 percent of those were at no risk of developing gene-related health problems. Cases of discrimination by employers have also been reported. There is a large amount of research aimed at discovering genetic differences in people's susceptibility to environmental chemicals, including chemicals found in the workplace, and it is likely that employers will want to use genetic tests to exclude those who are susceptible, rather than clean up their workplace.

If genetic testing becomes widespread, individuals may find themselves becoming socially stigmatized, due to rumors about their genetic constitution, and in the extreme case, a genetic caste system and even a genetic underclass may develop. Discrimination based on genetic screening has already been reported from USA when the African Americans who were detected to be carriers of the sickle cell anemia trait were denied admission in schools and jobs in military and aviation services.

The fear of discrimination amongst patients is so widespread that doctors are already reporting that patients are unwilling to take genetic tests for fear that it will affect their insurance prospects. In the USA with its private health insurance system this problem is particularly severe. In fact, scientists and doctors have taken the lead in calling for a ban on the use of genetic information by insurers.



Babies who have criminal genes (2020 AD)

Genetic Research and Local Population

Biotechnology is also international business. Even before transnational biotechnology companies can seek international markets among the affluent, they need research populations, now frequently drawn from among the world's poor. Research conducted across borders often targets local, relatively isolated populations whose homogeneous genetic pool provides a useful way to study disease and whose lack of power renders donors less able to negotiate for compensation or a share in benefits or profits. Moreover, research in other lands permits sponsors to evade human subject's protections that may obtain in their home countries. Human right activists have advocated just treatment of international research subjects and policy on access to post trial benefits. It is demanded that participants of such trials should have a share in prospective benefits. Voluntary informed consent in a culturally

appropriate mode be given by each participant, that members of control groups be provided with an effective treatment, if known, not merely a placebo; and that eventual benefits of the research should accrue to the research population after the trial, in accordance with its particular health needs. It is generally felt that genetic research conducted on local population should be based on benefit sharing, technology transfer, local training, joint ventures, provision of health care, or a cut of the royalties for humanitarian purposes

International Response

1997 European Convention on Human Rights and Biomedicine stated that: "We should protect the dignity and identity of all human beings", and demanded, "respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine". In the European and UN Documents the genome has been termed as the "common heritage" of all persons and not property open to commercial exploitation by a few. The UNESCO Universal Declaration on the Human Genome and Human Rights states that - 'The human genome underlies the fundamental unity of all members of the human family as well as the recognition of their inherent dignity and diversity. In a symbolic sense it is the heritage of humanity.'

Our hope is that knowledge of the genome will encourage some medical researchers to seek new interventions that are population based and that emphasis will be put on developing inexpensive drugs (comparable to aspirin and â blockers) and vaccines that prevent disease and disability in populations, rather than individual based designer therapies. If not, the human genome project has the potential to widen the apartheid in health care between rich and poor countries, and between the rich and poor within countries, more profoundly than anything previously seen in medicine. There is one overarching positive message for developing countries from the genome project. Though we are all virtually biologically identical, each of us is also unique. Tiny genetic differences exist between any two individuals, but these differences are no greater between people of different races than between those of the

same racial background. The unraveling of the human genome has thus removed forever any biological basis for racial discrimination.

Genomics the Future

The genetic revolution and the computer revolution are just now coming together to form a scientific, technological, and commercial phalanx, a powerful new reality that is going to have a profound impact on our personal and collective lives in the coming decades. The marriage of computers and genetic science, in just the last ten years, is one of the seminal events of our age and is likely to change our world more radically than any other technological revolution in history. We should have an informed, sober debate on the many issues raised by the genomic revolution.

The negative implications of genomics in no case should deter progress. As with all knowledge the genome can put to both good and bad use. The ultimate responsibility will rest with the scientists who will need to give it a certain direction and use its endless possibilities for the best of humankind. And the people at large, Peoples' Science Movement activists and committed politicians should fight the unethical business interests of the big corporations and support the international initiatives for humanizing the possibilities offered by the genomic revolution.

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2. Information Technology: Public Health Implections

Through the Internet, the public has now access to a growing supply of information on health and disease, often of variable quality and relevance. There are about 100,000 medical websites existing and their number is still growing rapidly. As a result, providing information on health will no longer be the exclusive remit of health care professionals. The quantity of information on the Internet will continue to grow over the next few years, as will the proportion of people with access to it.

Medical Information is one of the most retrieved types of information on the web. In fact according to a survey conducted recently 27% of female and 15% of male internet users say that they access medial information weekly or daily. An interesting observation from this and other surveys is that health and medical content seems to be one of a few categories in the internet that women are more likely to use than men. It is also found that in many countries proportionately more patients access health information from the internet than doctors.

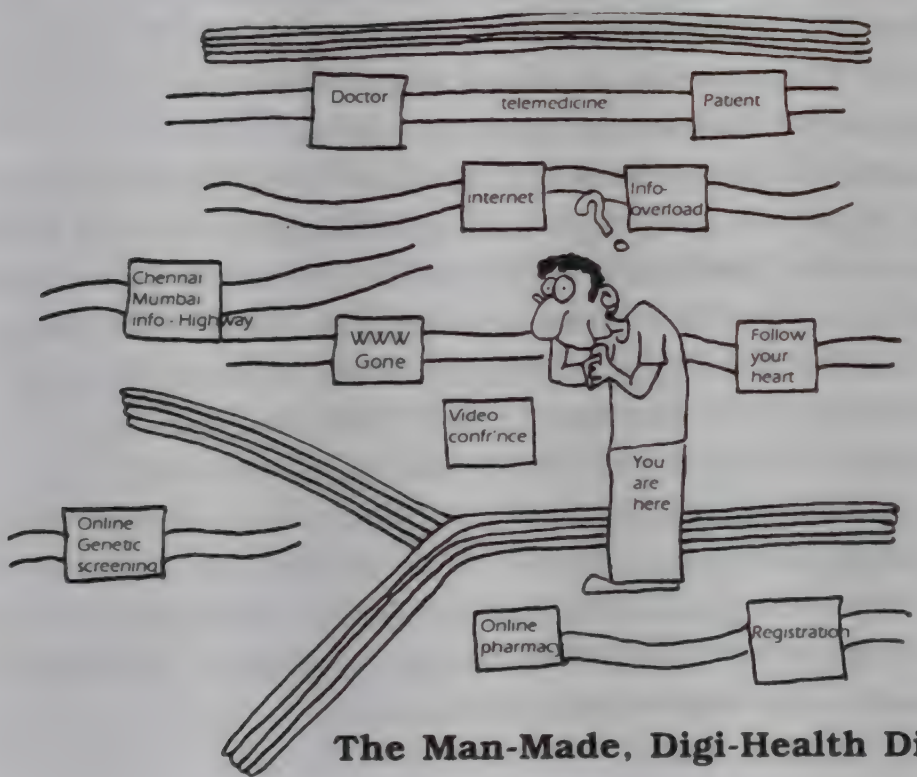
Consumer Empowerment

Health care information on the Internet has potential major benefits for patients. Numerous electronic discussion groups already allow patients to share experiences and some health related Internet sites offer email advice on a fee for service basis. A number of medical journals databases like MEDLINE, provide free access to health information. The fact that patients have access to the same databases as clinicians leads to increased consumer knowledge, consumer empowerment and consumer involvement, which is pushing clinicians to provide high quality health care. As physicians follow consumers into the information age this will further increase the demand for the provision of more health information on the Internet, leading to even more consumer empowerment and patient centered medicine leading to a positive feed back loop.

In internet the concept of 'prevention' and 'health promotion' which traditionally implied a formal communication process between the health professional as provider and the consumer as receiver is changing. Though there are a number of discussion forums conducted by committed doctors for patients on the internet health promotion and prevention is changing largely into a communication between consumer and consumer. This means that the original concept of public health as a process of enabling people to increase control over the determinants of health and thereby prevent disease or reduce the impact of disease mostly with the help only of the health professionals like doctors is changing.

The Challenges

But despite the obvious benefits, Medical Informatics presents many challenges, both to users and suppliers of the information. The Internet is accessible from most parts of the globe, and access and dissemination is largely uncontrolled and uncontrollable. Such an anarchic situation in this world of centralization of medial control has a democratic potential



The Man-Made, Digi-Health Divide

for decentralised information sharing. But the problems should not be overlooked. The main problem is that the quality of health information available in the net varies widely, from the most up to date practice guidelines produced by leading clinical bodies to out of date or inaccurate recommendations from various dubious agencies including drug companies.

Epidemic of Misinformation

There is a growing concern that Information Technology and its main application Internet can have deleterious effects on Public Health by its potential for spreading poor health information to the public. Reports of patients coming to harm because of the information obtained on the internet are already appearing. Several IT watchers have expressed the fear of the beginning of an epidemic of misinformation. Compared to the traditional media, electronic information can be infinitely duplicated at minimal cost and cheaply distributed. The largest cost is probably that of creating good and scientific information. Given the effort required to generate high quality information, it becomes cheaper to produce poor quality information that looks good than high quality information. Consequently, producers of poor information may be at an advantage on the internet and flood the market.

Recently a study to assess the reliability of healthcare information and how it may help lay people to cope with common health problem based on internet health information was conducted. 41 parent oriented Web sites giving health information relating to home management of fever in children were studied. Reliability of the information on the web sites was checked by comparison with published guidelines for the management of fever in children. It was found that only 4 web sites provided complete and accurate information for this common condition. Another study concluded that the health information available in the internet varies from the useful to the dangerous. This suggests an urgent need to check public oriented health care information on the internet for accuracy, completeness and consistency.

But due to lack of systematic studies about epidemiology in medical informatics it is hard to identify which information processes lead to unfavorable health outcomes. We may have to provide information 'tracers' into our information and communication systems and observe their effect as they course through the social decision making apparatus. We have to invoke a 'precautionary principle' acting now while the problem is potentially controllable and less risky than awaiting a situation that is out of control in future.

On Line Drug Stores

Another problem emerging in an alarming rate is direct to consumer advertising of drugs through internet. Apart from supplying dubious drug information through commercial websites masquerading as professional websites, drug companies have already started sale of prescription drugs over the internet. Food and Drug Administration (FDA) in USA is already investigating more than 200 websites suspected of selling unapproved or selling approved medication without valid prescriptions. A recent study by the University of Pennsylvania found 86 websites that sold Viagra, the sex potency drug without requiring a prescription. Twenty-two of the sites seemed to be outside the United States.

Many national governments have responded to this challenge. Former US President Bill Clinton during his tenure asked the US Congress for new laws to regulate the growing sale of prescription drugs over the internet. Online drug stores will be required to get approval from the FDA and to comply with state regulations on the practice of drug sales. Following Clinton's proposals civil penalties of up to $500,000 for selling prescription drugs to an individual without a valid prescription or for operating without federal certification will be charged in US now. US senate has approved the allocation of 10 Million dollars to hire 100 people and upgrade computer technology to investigate websites suspected of illegally dispensing prescription drugs.

Though the US initiative to curb on line sale of prescription drugs is welcome step cross border sale of drugs will take place making the control by national governments ineffective. This is more so in the case

of developing countries were drug control measures are already weak and ineffective.

Free Market Information versus Limited Health Resources

In countries where patients can participate in the choice of treatment the Internet could potentially be a rich source of information on treatment options, but meeting patients' expectations and managing their requests presents an important challenge for providers of health care especially in developing countries.

Hence, the widespread use of the Internet is likely to aggravate existing conflicts between patients' expectations and provision of health care. Patients will soon have access via the Internet to information on best practice from a variety of sources and will increasingly demand highly sophisticated medial care. But the health service's resources are limited, and it must attempt to ration treatment. Treatments that have been shown to be the most cost effective for a particular disease in population terms may be favored over treatments with greater efficacy at the individual level. This could cause conflicts between the informed desire of patients to obtain the 'best treatment' for themselves as individuals, and the system's inability to deliver not so cost effective health care. Conflicts are likely to arise where there is a free market in information and a controlled market in health care.

Physician Patient Relationship

Another level of conflict likely to emerge is between doctors and patients. Patients will be motivated to seek out the most recent literature for their condition. Many patients may become 'cyber hypochondriacs' and use the information gained from Internet to challenge the evidence base of physicians by confronting them with 'anecdotes' from the Internet. This is often referred to as being one of the negative sides of medical information on the Internet as it puts new strains on the patient-physician relationship. If the patients are confronting the doctors with 'good information' from the net there is not much of a problem. But since 'bad health information' put by vested interest groups like drug companies

and health equipment industries are also in plenty in the net, doctors will find it extremely difficult to have a scientific discussion with their patients.

Practice Guidelines

This problem has been recognized in the move towards providing quality medial care to patients now called evidence based medical practice. Pooled practice guidelines prepared by academic institutions and professional organisaitions for the management of various diseases will be scientific and an independent resource not only for doctors but also, in for patients as well. Faced with an enormous quantity of information of variable quality, and ill equipped to separate the wheat from the chaff, patients are likely to welcome access to guidelines that have been certified by recognized medical bodies.

Many see the development of protocol-based medicine, as the essential cultural change in clinical practice will permit the design of useful clinical information systems. The move to evidence based medicine makes it acceptable for clinicians to follow standard assessment and treatment protocols. In this case it is quite appropriate for clinicians to use information systems to help them.

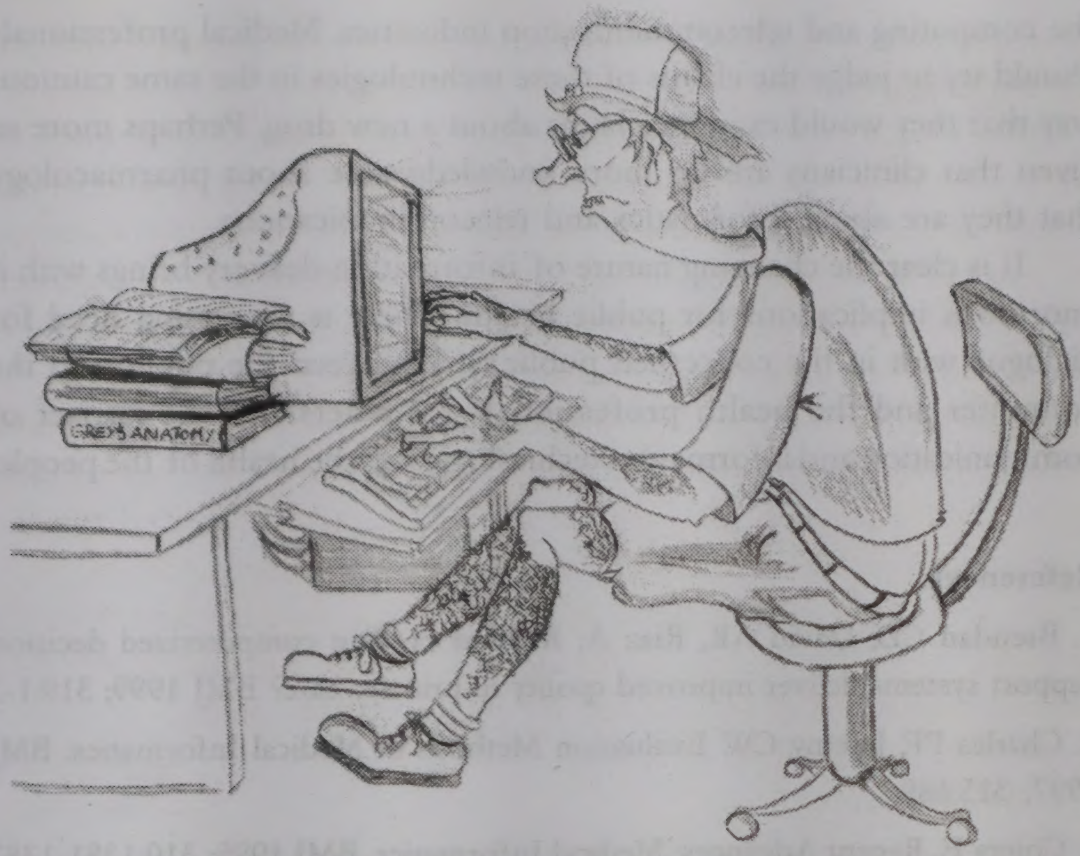
The ultimate goal of a protocol based decision system is to provide a set of tools that allows a clinician to access up to date guidelines and then apply them to the management of their patients. However, forgetting preplanned management tasks seems to be especially likely when making clinical decisions in high stress situations. It should be possible to make it easy for clinicians to access guidelines during routine care, making it less likely that steps will be inadvertently forgotten or altered. This will require the design of more complex systems that will be integrated into the electronic patient record such that protocols can be stored and manipulated by clinicians. For example best practice recommendations may need to be customized for local conditions or for individual patients. Furthermore, guidelines may be incorporated directly into patient records. When such systems become more commonplace, the collation of best

practice guidelines will have to be carried out by professional bodies and academic institutions.

This leads on to a another challenge posed to health care providers by the Internet: the mismatch in the speed with which new scientific results can be disseminated and the length of time required for doctors to start modifying their clinical practice based on such new information. Innovative approaches to scientific publishing may make it possible to use the Internet itself to redress this imbalance. It should at least be possible to provide guidance for Internet users on the best available sources of health care material.. The speed with which the Internet can deliver information should thus not be seen as a liability. Indeed, it offers a solution to some of the increasingly complex communication issues facing the health care system. If clinicians had routine access to the Internet, they could rapidly assimilate new information and change their clinical practice before it reached the media and the public.

Telemedicine

Telemedicine is basically the exchange of medical information at a distance. The information may be voice, an image, elements of a medical record, or commands to a surgical robot. Telemedicine aims to use communication of information to facilitate clinical care. Telemedicine was initiated for providing communication links between clinicians working in remote locations and experts in the advanced medical centers situated mostly in urban areas. The health care system in most countries is inefficient in communication infrastructure and telemedicine is seen as a new technology of reducing that cost. On the positive side recent experiences in some countries have identified benefits to remote telemedicine consultation. Services that provided isolated general practitioners with access to specialist skills had a beneficial effect. The skills of the general practitioners were increased by repeated interactions with specialists during the management of cases that were previously referred. This has arisen through the dynamics of the relationship between a remote general practitioner and a specialist. Both are motivated to form a coach and apprentice relationship for the immediate management of a patient.



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However, Telemedicine is now presented more in the guise of sophisticated new communications technology for specialist□ fs activities such as teleradiology and telepathology. Telecommunication companies champion these because they have the potential to become highly profitable businesses for them. Perhaps influenced by these forces, much of the research in telemedicine is driven by the possibilities of technology rather than the needs of clinicians and patients.

Conclusion

It is important to evaluate the claims made for these new technologies by those who seek to profit from them. Just as there is a longstanding symbiosis between the pharmaceutical industry and medicine, there is a newer and consequently less examined relation between medicine and

the computing and telecommunication industries. Medical professionals should try to judge the claims of these technologies in the same cautious way that they would examine claims about a new drug. Perhaps more so given that clinicians are far more knowledgeable about pharmacology that they are about informatics and telecommunications.

It is clear the changing nature of information delivery brings with it enormous implications for public health. There is a pressing need for dialogue with in the concerned public and between the public and the computer and the health professionals to understand the impact of communication and information technologies on the health of the people.

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